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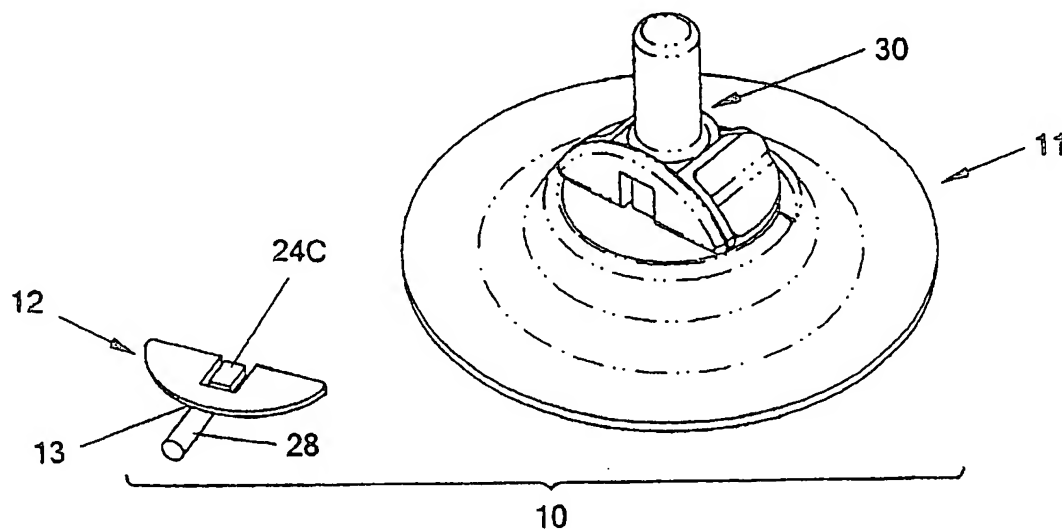
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(54) Title: LOW PROFILE PIVOTING JOINT INFUSION ASSEMBLY



(57) Abstract: System for the subcutaneous delivery into the body of a patient of a fluid from a remote vessel. The system includes a main assembly and placement member with a needle. A delivery tube for carrying the fluid is attached at a near end to the remote reservoir or vessel. At removed end, the delivery tube has a needle for engagement with the main assembly. The main assembly includes a rotating member that when the rotating is perpendicular to the main assembly, it will accept the handle and needle for emplacement of the body onto a patient. After the handle and needle are removed, the delivery tube can be attached to the rotating member which can then be rotated down to a position along to and adjacent the skin of the patient. This provides for a flush mounted infusion device.

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1 Title: Low Profile Pivoting Joint Infusion Assembly

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3  
4 This application claims priority to U.S. Provisional Application No. 60/259,971, filed  
5 January 5, 2001, and U.S. Patent Application No. 09/896,149, filed June 29, 2001, both of which are  
6 incorporated herein for all purposes.

7  
8 BACKGROUND OF THE INVENTION

9 The instant low profile, pivoting joint infusion assembly transports therapeutic fluids, such as  
10 insulin, from a remote, external source to a subcutaneous location in a patient's body with little or no  
11 leakage of fluids. The therapeutic fluid passes from the source, through a delivery tube, to a fluid  
12 infusion connection unit removably attachable to a therapeutic fluid infusion unit designed to be  
13 affixed to the patient's skin. The fluid infusion unit has a cannula insertable approximately normal to  
14 the skin to subcutaneously deliver the therapeutic fluid within the patient.

15 As is well known in the art, the cannula is generally a hollow, soft, flexible member which  
16 enters the skin through a passageway formed by a hollow, sharp-tipped, insertion needle. The  
17 insertion needle pierces the skin and subcutaneous regions of the infusion site allowing the cannula to  
18 pass therethrough. The needle is removed and properly disposed. Once the fluid infusion unit is  
19 connected to the patient, it generally remains in position. The connector assembly may be  
20 attached/detached as necessary to replace or change the therapeutic fluid being administered.

21 In the various embodiments of the present invention, a rotating member ensures accurate,  
22 positive alignment of fluid paths through the connection unit and the infusion unit.

23 Numerous approaches have been taken to provide quick-disconnect system for infusion  
24 therapy. U.S. Pat. Nos. 5,545,143 and 6,017,328 to Fishell disclose and teach such prior art systems.  
25 However, there are considerable drawbacks to the prior art systems; namely, the high cost of  
26 manufacturing an integral septum system within the main body or fluid infusion unit and the necessity  
27 for removably attaching the connector assembly through the top surface of fluid infusion unit, thereby

1 creating a higher profile for the entire infusion assembly when worn by the patient. It is well known  
2 that the higher the assembly's profile the more likely the assembly may be disturbed, exposed to  
3 unintentionally external contact, and dislodgment from the infusion site. Further, to ensure a leak-free  
4 infusion system, it is critical that there be positive alignment of the fluid infusion unit and the fluid  
5 connection assembly.

6 The various embodiments of the present invention solve the long-standing problems of the  
7 prior art devices. They achieve improved infusion therapies by, among other things, providing a safe,  
8 low-profile assembly wherein the therapeutic fluids may be administered, replaced, and changed  
9 quickly, securely, and confidently in an extremely low-damage exposure arrangement with little or no  
10 leakage of the therapeutic fluids to the environment.

#### 11 BRIEF DESCRIPTION OF THE DRAWINGS

12 Fig. 1 is a perspective view of one embodiment of the present system for the subcutaneous  
13 delivery of a therapeutic fluid showing the infusion unit with the emplacement member attached and  
14 showing the fluid infusion connection unit ready for attachment to the infusion unit.

15 Fig. 1A is a cross-sectional side elevation view of one embodiment of the infusion unit on  
16 the skin of the patient with the emplacement member attached.

17 Fig. 2 illustrates a top perspective view of the present system with the connection unit  
18 attached to the infusion unit in the fluid delivery position.

19 Fig. 2A shows a cross sectional side elevation view of one embodiment of the present system  
20 in the fluid delivery position.

21 Fig. 3 illustrates a top side perspective view of one base of the present system.

22 Fig. 3A shows a bottom side perspective view of the base of Fig. 3.

23 Fig. 4 is a top perspective view of a body section of the present system.

24 Fig. 4A shows a cross sectional view of a body section.

25 Fig. 5 is a perspective view of a rotating member of the present system.

26 Fig. 5A is a cross sectional side elevation view of the rotating member of Fig. 5.

27 Fig. 6 shows a top perspective view of a cover of the present system.

1           Fig. 6A illustrates a bottom perspective view of the cover of Fig. 6.

2           Fig. 7 is a top perspective view of a fluid infusion connection unit with a delivery tube

3   attached.

4           Fig. 7A is a bottom perspective view of the unit of Fig. 7.

5           Fig. 7B is a cross sectional side elevation view of the unit of Fig. 7.

6           Fig. 8 is a bottom perspective view of a plug of the present system.

7           Fig. 8A is a top perspective view of the plug of Fig. 8.

8           Fig. 9 is a cross sectional view of the system illustrated in Fig. 2.

9           Fig. 9A is a first side perspective view of an emplacement member of the present system.

10          Fig. 9B is a second side perspective view of the emplacement member of Fig. 9A.

11          Fig. 10 is a perspective view of a second embodiment of the present system showing a

12   second embodiment infusion unit with a second embodiment emplacement member attached and a

13   second embodiment fluid infusion connection unit ready for attachment to the second infusion unit.

14          Fig. 10A illustrates a cross sectional view of a second embodiment of the infusion unit with

15   the second embodiment emplacement member attached.

16          Fig. 10B is a cross sectional view of a second embodiment of the present system in the fluid

17   delivery position.

18          Fig. 10C shows cross sectional view of a second embodiment of the present system with a

19   locking member for securing the rotating member.

20          Fig. 10D is a cross sectional view of a second embodiment of a rotating member for the

21   present system.

22          Fig. 11 is a top perspective view of a second embodiment fluid connection unit.

23          Fig. 11A is a cross sectional view of the unit of Fig. 11.

24          Fig. 12 is a cross sectional side elevation view of a third embodiment of the present system

25   showing a third embodiment emplacement member attached to a third embodiment infusion unit.

26          Fig. 12A shows a cross sectional view of a third embodiment in a fluid delivery position.

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1            Fig. 12B is a partial cross sectional view of one position of the valving of a third embodiment  
2 of the present system.

3            Fig. 13 is a top perspective view of a fourth embodiment of the present system in the fluid  
4 delivery position.

5            Fig. 13A is a bottom perspective view of the embodiment of Fig. 13.

6            Fig. 13B is a top plan view of the embodiment of Fig. 13.

7            Fig. 13C is a cross sectional view taken along line B-B of Fig. 13B.

8            Fig. 13D is a cross sectional view taken along line A-A of Fig. 13B:

9            Fig. 13E is a top perspective view of a fourth embodiment of the infusion unit of the present  
10 system.

11           Fig. 13F is a bottom perspective view of the embodiment of Fig. 13E.

12           Fig. 13G shows an exploded top perspective view of a fourth embodiment rotating member.

13           Fig. 13H illustrates a bottom perspective view of a fourth rotating member embodiment.

14           Fig. 13I illustrates a cross sectional view of the rotating member of Fig. 13H.

15           Fig. 13J is a bottom perspective view of a fourth embodiment cover of the present system.

16           Fig. 13K shows a top perspective view of a fourth embodiment fluid connection unit.

17           Fig. 14 illustrates in cross section a fifth embodiment of an infusion system of the present  
18 invention in the fluid delivery position.

19           Fig. 14A shows in cross section a fifth embodiment with a "T" shaped rotating member.

20           Fig. 14B is a perspective view of a "T" shaped rotating member of the present system.

21           Fig. 15 shows a cross sectional side elevation view of a sixth embodiment of an infusion unit  
22 with an emplacement member attached.

23           Fig. 15A is a top perspective view of a sixth embodiment of the present system in a partially  
24 rotated position.

25           Fig. 15B is a cross sectional side view of the embodiment of Fig. 15A.

26           Fig. 15C is a top plan view of a sixth embodiment in the fluid delivery position.

27           Fig. 15D is a cross sectional view taken along line A-A of Fig. 15C.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 illustrates a first embodiment of the present invention showing the pivoting joint infusion assembly 10 having a main fluid infusion unit 11 and an infusion fluid connection unit 24. The fluid infusion unit 11 is shown in Fig. 1 with a main fluid infusion unit emplacement member 30 attached to the unit 11 as would be the situation when the unit is ready for placement on the patient's body. The connection unit 24 is shown with a portion of the fluid delivery tube 28 attached to the first end 13 of the connection unit 24. Opposite the first end is a rotating member attachment portion 24C which may be connected to the infusion unit after the emplacement member is withdrawn.

Fig. 1A shows a cross-sectional, side elevation view of the main fluid infusion unit 11 with the emplacement member 30 attached thereto. Fig. 1A shows the assembly 10 in a first emplacement position. The emplacement member 30 has a head section 30A with an insertion needle 32 securely attached to the head section. The distal end 32A of the needle extends through the main fluid infusion unit 11 and extends beyond the distal end of the downwardly depending cannula 14C attached to the underside 12C of the infusion unit 11. Cannula 14C has longitudinal cannula axis  $A_c$ . In order to attach the infusion unit 11 to the patient, the underside 12C (generally having an adhesive applied thereto) is pressed against the patient's skin 7 with the needle 32 puncturing the skin and allowing the cannula 14C to slide subcutaneously into the infusion site. The emplacement member 30 is then withdrawn and discarded, including the needle 32, and the infusion unit 11 remains in place with the cannula 14C in fluid communication with the patient's body.

Infusion unit 11 has a main assembly body 12 as seen in Fig. 1A. Cooperating with the main assembly body 12 is a base 14 into which seats a rotating member or pivoting joint 16 overlain at a first end 16A with a joint retaining cover 22. Rotating member 16 also has an engagement arm 16C for receiving the rotating member engagement portion 24C of the infusion fluid connection unit 24 as will be discussed below. Engagement arm 16C has a longitudinal arm axis,  $A_R$ .

Turning again to the base 14, it is insertable through the underside 12C of the body 12 whereby it cooperates with the joint retaining cover 22 to "sandwich" or enclose the first end 16A of rotating member 16. Thus, the base and cover have complimenting inner arcuate surfaces to allow the

1 joint 16 to pivot. In the embodiment of Fig. 1A, the joint 16 includes a first septum 18 and a second  
2 septum 20. The first septum 18, after removal of the emplacement member needle 32, will eventually  
3 receive a delivery needle 26 on the fluid connection unit 24. This will allow for delivery of the  
4 therapeutic fluid from the remote source into the rotating member 16 then through the cannula 14C  
5 and into the patient's body. As will be seen below, not all embodiments of the present invention  
6 require the fluid to pass through the rotating member 16.

7 Fig. 1A shows the insertion needle 32 penetrating the first septum 18; extending through the  
8 engagement arm 16 along longitudinal arm axis  $A_R$ ; penetrating the second septum 20; continuing  
9 through the cannula along the longitudinal cannula axis  $A_c$ ; extending beyond the distal end of the  
10 cannula; and penetrating into the patient's subcutaneous tissue. A plug 25 engages the engagement  
11 arm 16C of the rotating member 16 and acts as a guide for receipt of emplacement member 30.

12 Fig. 2 is a perspective view of an embodiment of the present system 10 with the  
13 emplacement member removed and the infusion fluid connection unit 24 removably attached to the  
14 main fluid infusion unit 11. The fluid delivery tube 28 is attached to provide for the flow of  
15 therapeutic fluid from the remote source to the patient.

16 Fig. 2A is a cross-sectional, side elevation view of the assembly 10 in a second delivery  
17 position. As may be seen in Fig. 2A, connection unit 24 has been attached to the rotating member 16  
18 and rotating member 16 has been pivoted  $90^\circ$  to a second position. Thus, a comparison of Figs. 1A  
19 and 2A discloses that the rotating member 16 is pivotable from a first position wherein the  
20 longitudinal arm axis  $A_R$  is coincident or parallel and aligned with the longitudinal cannula axis,  $A_c$  to  
21 a second position wherein the longitudinal arm axis,  $A_R$ , is perpendicular to the longitudinal cannula  
22 axis,  $A_c$ . As will be described below, when the connection unit 24 is attached to the rotating member  
23 16 in this rotating member second position, the assembly 10 is positioned to deliver therapeutic fluid  
24 into the patient's body in what is called a delivery position.

25 The rotation of member 16 from the first position to the second position ensures the accurate  
26 alignment of the fluid flow path from the source to the patient with little leakage.

1 Figs. 3 and 3A illustrate a base 14 whose function is to locate ball joint or rotating member  
2 16 within main assembly body 12 and to provide engagement with the ball joint and to accommodate  
3 fluid communication between the ball and the vertically oriented cannula 14C, depending from a  
4 bottom surface 14B of the base. The base is also seen to have perimeter walls 14A describing a  
5 generally circular structure having a bottom surface 14B and a top surface 14G. Descending from the  
6 bottom surface 14B is the aforementioned cannula 14C which is attached to the base 14 near the  
7 center of the bottom surface 14B at a proximal end thereof, the cannula 14C being a cylindrical,  
8 hollow sheath structure having a distal end 14E having a conical cross section (see Fig. 3A). The  
9 function of the cannula 14C is to carry a fluid received from the ball joint 16 into the body of the  
10 patient. Thus, the base has a ball joint seat 14I in the top surface 14G thereof which corresponds to  
11 the outline of the ball joint 16. Cutouts 14H, located around the perimeter of top surface 14G, are  
12 provided to enclose legs (12F, 12G, 12H, and 12I) of base 12 (Fig. 4). Base 14 is also seen to include  
13 a boss 14F along the perimeter walls, the boss 14F for seating into notched-portion 12O of main  
14 assembly body 12. Apertures 14M are for receiving the receiving legs (22E, F, G, and H) of cover 22  
15 (Fig. 6). Thus, it is seen that ball joint seat 14I is more particularly designed to receive ball joint 16,  
16 providing as part thereof ball joint engagement arm recess 14J for receipt of ball joint main body 16A  
17 thereinto, support on recesses 14K for receipt of support arms 16B therein (Fig. 5), and engagement  
18 arm recess 14L for receipt there into of engagement arm 16C of ball joint 16.

19 Turning now to Figs. 4 and 4A, a main assembly body 12 is illustrated, the purpose of which  
20 is to provide a structure on which to locate the other assemblies of the fluid infusion unit 11, and to  
21 provide a bottom surface 12C attachable through an adhesive to the skin of a patient. Fig. 4A shows  
22 the main assembly body 12 as generally disc-shaped and having a low profile. The main assembly  
23 body 12 is typically approximately .8-inches in diameter with a height of about .29-inches. The novel  
24 design has achieved both a "low profile" (a height lower than approximately .30-inches) and a small  
25 "footprint" which has a radius of about .8-inches and a surface area of about .55 square inches. This  
26 provides what is generally described as a "small footprint." One embodiment of the invention  
27 provides a width-to-height ratio of approximately 2.75 to 1 (or lower).



1           The main assembly body 12 has a perimeter 12A and a top surface 12B, the top surface 12B  
2 including raised walls 12K, including walls 12D, defining a central opening 12E, into which is  
3 inserted from the under side thereof, the base 14. The main assembly body 12 includes legs (12F, G,  
4 H, and I) having apertures 12J therein, which legs receive cutouts 14H of the base when the base is  
5 inserted upwards through the bottom of the main assembly body 12 into central opening 12E with  
6 apertures 12J aligned with apertures 14M of the base, and with notched-portion 12O of main  
7 assembly body 12 for receipt of boss 14F of base 14. With base 14 properly inserted into central  
8 opening 12E from below main assembly body 12, cutouts 14H and legs (12F, G, H and I) will seat  
9 together and cannula 14C will be seen to project below main assembly body 12, as is best seen with  
10 reference to Figs. 1 and 1A. Main assembly body 12 includes upper lip 12L and fluid connector  
11 cutout 12M for engaging the fluid connector cover 24A and also feed tube engagement cutout 12N.  
12 In this configuration, it can be seen that a pivoting or ball joint 16, as more specifically described in  
13 Figs. 5 and 5A, can be placed in ball joint seat 14I of base 14, as more specifically set forth in Fig. 3.

14           Figs. 5 and 5A show the structure and components of the ball joint. Ball joint 16 typically  
15 includes at least partly a spherical main body 16A which is seen to have projecting therefrom  
16 cylindrical, opposed support arms 16B and, on an axis perpendicular to the axis described by the  
17 support arms 16B; this is seen to have an engagement arm 16C. Support arms 16B support the ball  
18 joint within support arm recesses 14K of the base 14 and also, within support arm cutouts 22J of cover  
19 22 (Fig. 6A). Engagement arm 16C is also seen to have a ball joint guide member 16D on a portion  
20 thereof and a longitudinal arm axis  $A_R$ . This will be seen to provide engagement with both the plug  
21 25 and when the plug 25 is removed, with the fluid connection unit 24 (see ball joint guide notch  
22 cutout 24D in Fig. 7).

23           Fig. 5A shows in cross section that the interior of ball joint 16 includes a central channel or  
24 bore 16E having an enlarged or cut out first end 16F and an enlarged or cut out second end 16G and a  
25 central portion 16H between the first end and the second end. Generally perpendicular to the central  
26 bore 16E and connected with the central portion 16H thereof is a feed channel bore 16I which  
27 communicates with the surface of the ball body of the rotating member 16 at aperture 16J. Further, it

1 is seen that the first septum 18 seats recessed within enlarged or cut out first end 16F and second  
2 septum 20 seats snugly within enlarged second end 16G. There is a neck 16Z between ball joint main  
3 body 16A and engagement arm 16C.

4 Figs. 6 and 6A illustrate details of the cover 22. Fig. 6 is a top side perspective view while  
5 Fig. 6A is a bottom side perspective view. The cover 22 is generally disc-shaped and designed to fit  
6 in the central opening 12E of the main assembly body 12, as seen in Fig. 1A, such that legs (22E, F,  
7 G, and H) are insertable through apertures 12J in each of main assembly body legs (12F, G, H, and I)  
8 and further, such that legs (22E, F, G and H) extend through the main assembly body legs and into  
9 base 14 at apertures 14M in the base. Thus, legs (12F, G, H and I) of main body 12 and legs (22E, F,  
10 G and H) of cover 22 engage one another and base 14 to sandwich ball joint 16 within central  
11 opening 12E and between the base 14 and the cover 22.

12 Fig. 6 shows that cover 22 is generally disc-shaped and includes a top surface 22A and  
13 perimeter walls 22B, the perimeter walls 22B being designed to engage the walls 12D defining  
14 central opening 12E of body 12. Cover 22 is in Fig. 6A to have a lower surface 22C. Projecting from  
15 the lower surface 22C are the aforementioned cylindrical legs (22E, F, G and H) dimensioned to  
16 engage both the apertures 12J of the main assembly body 12 and apertures 14M of the base. Cover 22  
17 is also seen to have defined on a lower surface thereof, a recessed portion or ball joint seat 22I, the  
18 ball joint seat 22I including recess for ball joint support arm cutouts 22J and ball joint engagement  
19 arm cutouts 22L. The lower surface 22C of the cover also includes a neck cutout 22K, for allowing  
20 the ball joint 16 to rest in an up position (see Fig. 1A), and a ball joint seat 22I where a ball joint 16  
21 may rest. Moreover, it is seen that ball joint seat 22I is configured such that the ball joint 16 may be  
22 pivoted in a plane parallel to that of the cover surfaces 22A and 22B (a "down" position)(see Fig. 2A)  
23 and thus, rest with the engagement arm 16C of the ball joint 16 in ball joint engagement arm cutout  
24 22L or, the ball joint 16 may be rotated to a position perpendicular thereto, as is illustrated in Fig. 1A,  
25 such that the engagement arm 16C rotates out of engagement arm cutout 22L and stands  
26 perpendicular to top surface 22A. Further yet, it is seen that cover 22 includes fluid connector locking

1 boss coves 22M for lockingly maintaining the fluid connector in a down or "use" position as set forth  
2 in more detail below and with reference to Fig. 9.

3 Figs. 7, 7A and 7B illustrate the infusion fluid connection unit 24. The function of unit 24 is  
4 to provide a means for delivery of a fluid to the remaining elements of the infusion assembly 10 to  
5 ultimately reach the patient through the cannula 14C. The general method of doing so is to connect a  
6 feed tube 28 bearing a fluid therein to a needle 26 having a removed end 26A. The needle 26 will  
7 penetrate first septum 18 to deliver a fluid into the central bore 16E of the ball joint 16 for delivery  
8 through feed bore 16I to cannula 14C as set forth in Fig. 2A. Note that the first septum is "self  
9 sealing" such that when needle 26 is removed, for example, temporarily when a patient wishes to  
10 leave his or her bed, no fluid that has left the needle and is in the injection assembly will escape.

11 Fluid connection unit 24 has a semi-circular shape cover plate 24A defining a cover  
12 perimeter 24B. The cover cooperates with the flat shoulder 22A of the main body 12. Projecting  
13 from the cover 24A are walls defining a rotating member engagement portion 24C, these walls  
14 contiguous with a ball joint guide cutout 24D. When the fluid connection unit 24 is engaged to the  
15 ball joint so that needle 26 penetrates the first septum, engagement portion 24C will partially enclose  
16 the engagement arm 16C such that ball joint guide member 16D is seated snugly within ball joint  
17 guide cutout 24D. It is also seen in Fig. 7A that fluid connection unit 24 includes, on walls  
18 perpendicular to cover 24A, a pair of oppositely disposed locking bosses 24F for locking engagement  
19 with fluid connection boss coves 22M of cover 22 when fluid connection unit 24 is in a down or use  
20 position, as set forth in Fig. 9. There are a number of advantages to the fluid engagement means,  
21 which consists of a pair of locking bosses 24F releasably engaging fluid connection boss coves 22M.  
22 First, there is the tactile "feel" that the patient will get when the bosses "pop" into the coves. Second,  
23 there is the audible "click" that occurs when the bosses "pop" into the coves. Both of these sensory  
24 signals are important to assure the patient that the fluid connection unit 24 is locked onto the main  
25 infusion unit 11 and locked down to ensure communication with the cannula 14C, thus ensuring that  
26 the fluid flowing through the delivery tube is in fact flowing through the cannula 14C and into the  
27 patient. Such a releasable, positive lock down system helps prevent accidental dislodgings of the

1 tubing. Further, the system of a ball joint guide cutout 24D and ball joint guide member 16D provides  
2 for easy and effective alignment of fluid connection unit 24 to the engagement arm 16C of the ball  
3 joint 16 to easily and positively affix the infusion tubing to the assembly via a keyed mating of the  
4 tubing to the ball joint 16. The present system 10 removes the tubing from the main assembly body  
5 12 and does not leave a "tail" of delivery tubing as is found in prior art systems which provide  
6 disconnect spliced into the delivery tube itself, rather than at the removed end.

7 It is seen with reference to Figs. 7, 7A and 7B that fluid connection unit body 24E includes  
8 feed tube engagement collar 24G to receive the end of feed tube 28 and to provide a sealed mounting  
9 boss for needle 26. Thus, a function of fluid connection unit 24 is to provide means to receive the  
10 feed tube 28 in fluid tight relation and to mount needle 26 therein in a manner that will allow the  
11 needle 26 to align properly with the ball joint 16. Further, it allows the fluid connection unit 24 to  
12 move down and lock as it is joined to the ball joint 16 in a down, folded or use position, as seen in  
13 Fig. 9.

14 Turning now to Figs. 8 and 8A, details about the plug 25 may be appreciated. The functions  
15 of plug 25 are several. The first is to provide a means to effectively guide the emplacement member  
16 30 and needle 32 through the two septums and into the cannula 14C when fluid infusion unit 11 is  
17 first engaged in the body of the patient, thereafter when the emplacement member 30 is removed from  
18 the infusion unit and discarded. A second function of the plug 25 is to provide a means to seal off the  
19 distal end of the engagement arm 16C when the fluid connection unit 24 is removed therefrom. It  
20 may be appreciated that plug 25 may fit snugly against the first septum 18 when the fluid connector is  
21 removed therefrom to keep dust and air from reaching that surface.

22 It is seen in Figs. 8 and 8A that plug 25 includes a cover portion 25A defined by a cover  
23 perimeter 25B, the cover being semi-circular in shape, the shape of the plug 25 being substantially  
24 identical to the fluid connection cover plate 24A, both of these covers being dimensioned to fit within  
25 fluid connector cutout 12M of upper lip 12L of main body assembly (see Figs. 4 and 4A). That is,  
26 when either the fluid connection unit 24 or plug 25 are connected to engagement arm 12C of ball joint  
27 16 and ball joint 16 is in a folded or down position as is set forth in Fig. 2A, then either of the covers

1 will fit snugly within cutout 12M of main assembly body 12 such that perimeter 24B or 26B, as the  
2 case may be, will be flush with upper lip 12L of main assembly body 12.

3 Plug 25 also includes an emplacement member plug portion 25E and needle guide portion  
4 25G. As was seen in Fig. 1A, portion 25E will fit snugly within emplacement member 30 and needle  
5 guide portion 25G of plug 25 will fit snugly within first end 16F of central bore 16E of engagement  
6 arm 16.

7 Fig. 9 illustrates a cross sectional view of a first embodiment of the present invention with  
8 the fluid infusion connection unit attached and the assembly in the fluid delivery position.

9 Emplacement member 30 is illustrated in Figs. 9A and 9B. A function of member 30, as set  
10 forth earlier, is to provide a means through use of needle 32 having pointed end 32A for inserting the  
11 cannula 14C under the skin of the patient prior to commencement of delivery of the fluid thereinto.  
12 Thus, member 30 is seen to include a long, sharp needle 32 having a pointed distal end 32A and a  
13 proximal end 32B where it joins the head of the member. Member 30 further includes a cylindrical  
14 elongated grasping head 30A and walls defining a guide cutout 30B. The member also includes  
15 vertical walls 30C and, perpendicular thereto, a base 30D. Adjacent and removed from the grasping  
16 head are a pair of parallel side walls 30E. Side walls 30E engage the plug 25 as set forth in Fig. 1A  
17 and 1B to seat needle 32 in plug opening 25H. Thus, the purpose of the member 30 is to cooperate  
18 with the plug 25 to maintain the needle 32 with elongated opening 25H which is itself aligned with  
19 the longitudinal axis of cannula 14C. When member 30 is inserted through the two septums its  
20 central longitudinal axis will be coincident with the longitudinal axis of cannula 14C. Further, the  
21 depth to which the member 30 is inserted is sufficient so the needle pointed end 32A projects just  
22 beyond the distal end of cannula 14C as seen in Fig. 1A. The cannula 14C is perpendicular to the  
23 lower surface of the infusion unit 11. This makes for efficient emplacement of the infusion unit onto  
24 the patient. When the delivery tube 28 is attached through the fluid connection unit 24 into the main  
25 body 12 of the fluid infusion unit 11, the tube 28 is perpendicular to the cannula 14C and almost flush  
26 with the skin. The present infusion assembly 10 is unique in providing a cannula projecting  
27 perpendicular into the surface of the skin while providing delivery tube that joins the assembly body

1 perpendicular to the cannula and almost flush with the skin. This helps provide a "low profile" and a  
2 "snag free" assembly.

3 It should be noted that any or all parts of the invention may be made from anti-bacterial  
4 materials known in the trade. Further, the invention provides a fluid infusion assembly 10 with a ball  
5 joint 16 that is rotatable between a first position parallel to and coincident with the cannula 14C to a  
6 second perpendicular arrangement. In an alternate preferred embodiment, snaps, detents or other  
7 means to releasably retain the ball joint 16 in the perpendicular fluid delivery position, the parallel  
8 position and also a position half-way between the two, or at 45 degrees with respect to the  
9 perpendicular. This provides an additional position should the patient want to use the assembly  
10 without the ball joint 16 being either perpendicular or parallel.

11 Fig. 10 shows an alternative infusion assembly 110 having a main infusion unit 111 and a  
12 fluid infusion connection unit 124. An emplacement member 130 is shown affixed to the body 112 of  
13 the unit 111 with cannula 114C projecting perpendicularly downward from the bottom surface 114B  
14 of base 114. As discussed above relating to another embodiment 10 of the invention, the insertion  
15 needle 132 extends beyond the distal end of the cannula. A two-piece cover 122' and 122" engages  
16 the base 114 and retains a rotating member 116 (Fig. 10A) within the main body 112.

17 The embodiment of Fig. 10 includes a lock 117 which will securely maintain the rotating  
18 member 116 in a "down" or locked position (Fig. 10B). Figs. 10 and 10A illustrate the lock 117 in an  
19 unlocked, or disengaged position.

20 Fig. 10A for this embodiment 110 corresponds generally with Fig. 1A for the first  
21 embodiment 10. It should be understood that the same basic principals of operation are involved in  
22 these two embodiments. The fluid infusion unit 111 is attached to the patient by use of the  
23 emplacement member in cooperation with the cannula. Once the infusion unit is attached to the  
24 infusion site, the emplacement unit is discarded and the fluid connection unit 124 is attached to the  
25 rotating member 116. The rotating member is pivoted from a first position to a second position  
26 whereby therapeutic fluid from a remote source may be delivered subcutaneously to the patient's  
27 body. While the rotation of rotating member 116 ensures proper alignment of the fluid flow passages

1 as was achieved with the first embodiment 10, the locking system 117 in this embodiment 110 results  
2 in a positive securing of the assembly in a fluid delivery position as shown in Fig. 10B.

3 Fig. 10A illustrates the infusion unit 111 with the emplacement member 130. Base 114 has  
4 perimeter walls 114A, bottom surface 114B, top surface 114G ball joint support arm recesses,  
5 pivoting joint body recess, engagement arm recess, apertures, and pivoting joint seat 114I in a manner  
6 as discussed with the first embodiment of unit 11. The function of the base 114 is the same as  
7 previously discussed. First, base 114 provides support for rotating or pivoting joint 116. Further,  
8 pivoting joint seat 114I and pivoting body recess provide support for rotating joint 116 whatever  
9 position the rotating joint 116 happens to be in. Furthermore, walls 114A of base 114 are configured  
10 to at least partially accept rotating joint 116 when it is in a down position. There are additional  
11 features to base 114 illustrated in Figs. 10A and 10B that are not found in the first embodiment 14.  
12 For example, Fig. 10B shows that base 114 provides a lock stop 114N. Stop 114N acts as a stop  
13 against which lock 117 may rest. Fig. 10C shows base 114 has walls defining left channel 114O  
14 which engage the lock 117 to the base 114. As the lock 117 slides in channel 114O it will be  
15 prevented from backing out from the base by walls partially blocking these channels. Further, base  
16 114 includes land 114P, also for accepting and guiding lock 117 between an "in" and an "out"  
17 position.

18 In the previous embodiment the functionally similar structure was sometimes referred to as a  
19 "ball joint" and is here being called a "pivoting" or "rotating" joint 116 in an effort to point out that  
20 while a "ball" shape, may, in part, provide for pivoting, in fact, the particular geometry of the  
21 structure is not crucial to its rotating nature. That is, rotating joint 116 is, similar to the ball joint 16, a  
22 rotating element which has channels within which will allow the insertion of an emplacement member  
23 through the joint when the joint is in a first position and, upon rotation will allow connection between  
24 a fluid infusion connection assembly and the cannula when it is in a second position, typically rotated  
25 any number of degrees, for example 90° from the first position. Ball joint or pivoting joint 116 is seen  
26 in Fig. 10D to have, typically, at least a partially spherical portion 116A and a pair of support arms  
27 (not shown). The support arms and at least part of the spherical portion 116A will rest in portions of

1 base 114 as will be understood by reference to the figures. Engagement arm 116C will be seen to  
2 have central bore 116E and central portion 116H of central bore 116E aligned coincident with the  
3 longitudinal axis  $A_R'$  of the engagement arm 116C. The axis of support arms is perpendicular to the  
4 axis of engagement arm 116C. Thus, the general design of the pivoting or rotating members of these  
5 embodiments includes two bores through the body of a pivoting member which are perpendicular to  
6 one another and to the axis of rotation, the two bores or channels for carrying fluid from a fluid  
7 connector to the cannula. Perpendicular to one of those two bores will be a central bore to carry the  
8 insertion needle for placement of the device on the skin of the patient.

9 As will be noted below there are embodiments of the present invention in which the rotating  
10 member does not have any bores or septums.

11 Ball joint or pivoting joint 116 is also seen to have guide member 116D which assists in  
12 engaging and guiding fluid connection unit 124 onto pivoting joint 116. Pivoting joint 116 and ball  
13 joint 16 both contain a similar arrangement of channels or bores throughout the body thereof. The  
14 purpose of these is twofold. First, a bore must be provided such that when the joint is in an up or  
15 vertical position a handle is engaged therewith, the handle having an insertion needle projecting  
16 downward through the cannula. The second function of the bores or channels in the body of the  
17 pivoting joint is for carrying fluid from the fluid connector to the cannula. The central bore 116E  
18 including central portion 116H will carry the needle of the handle when the device is placed on the  
19 patient. At least part of the central bore of pivoting member 116 will also provide for carrying fluid to  
20 the patient. However, pivoting member 116 provides, perpendicular to the central bore, a feed  
21 channel bore 116I which completes the necessary passageway to carry fluid from the fluid connection  
22 unit to the cannula (and into the patient) when the pivoting member or ball joint is in a down position.  
23 It is noted here that the pivoting or ball joint typically rotates about an axis perpendicular, and going  
24 through, the junction of the central bore and the feed channel bore.

25 Note with reference to Fig. 10D that pivoting joint 116 has a first cutout 116F and a second  
26 cutout 116G the first cutout 116F being at the first end and the second cutout 116G being at the  
27 second end, the two cutouts dimensioned for receipt of septums thereinto (see Fig. 10A). First cutout



1 116F brings the septum in from the side of the engagement arm instead of from the front engagement  
2 arm as set forth in the earlier embodiment. Ball joint or pivoting joint 116 also has an aperture 116J at  
3 the end of feed channel bore 116I for carrying fluid into the patient when the pivoting joint 116 is in a  
4 down position (see Fig. 10B).

5 Turning now to fluid infusion connection unit 124, and Figs. 11 and 11A, it is seen that unit  
6 124 is designed to carry fluid into pivoting joint via a connection of a needle piercing the first septum  
7 118 (see Fig. 10A). Fluid connection unit 124 includes a cover plate 124A having a cover perimeter  
8 124B. The connector 124 also has a body portion 124E and extending from the body portion is a feed  
9 tube engagement collar 124G for engagement with a flexible feed tube 128. The feed tube will carry  
10 fluid and joins the needle 126 in feed tube engagement collar 124G. It is seen that needle 126 is held  
11 in body channel 124Z such that the feed tube engages the needle 126. Body portion 124E contains  
12 slots which slots will engage the outer edges of engagement arms 116C. Note that "V" shaped  
13 pivoting joint guide notch cutout 124D will guide "V" shaped fluid connection unit onto a "V" shaped  
14 engagement arm 116 of the pivoting joint while aligning needle 126 with the first septum of the  
15 pivoting joint and the central bore. Moreover, body 124E includes land 124X that will seat within of  
16 the engagement arm recess of base 114 when the connector is pushed onto the engagement arm and  
17 then the engagement arm is rotated to a down position (see Fig. 10B). Fluid connection unit 124 is  
18 typically urged onto the engagement arm when the engagement arm is in a 45° or a vertical position  
19 (Fig. 10A) until it is flush and then the joint is rotated to a down or 0° position (see Fig. 10B). This  
20 rotation of the coupled unit 124 and ball joint 116 should be done with the lock 117 in an "out" or  
21 disengaged position. When the coupled fluid connection joint engagement arm unit is rotated down,  
22 lock 117 can be slid forward until it is fully engaged against stop 114N and nose 117A overlies at  
23 least a portion of the rotating unit 116. When the lock 117 is moved forward it will hold down the  
24 pivoting joint 116.

25 Figs. 12, 12A and 12B illustrate another alternate preferred embodiment of a fluid infusion  
26 assembly 210 which includes a rotating joint 216 which contains a slide valve 250 which slides back  
27 and forth in a slide valve chamber 252. The slide valve 250 includes a valve body 254 which includes

1 walls defining a channel 256. The valve body 254 is designed to snugly fit adjacent the walls defining  
2 slide valve chamber 252. Slide valve 250 may slide back and forth in slide valve chamber 252 on a  
3 "living" hinge 257. In an "out" position as illustrated in Fig. 12, the slide valve body urged by hinge  
4 257 blocks the channel of central portion 216H of central bore of joint 216. This is the position of the  
5 slide valve when fluid connection unit 224 is engaged therewith but rotating joint 216 in an "up"  
6 position, or, in fact, in any position but down. Note however that when fluid connection unit 224 is  
7 rotated to a down position such as illustrated in Fig. 12B, then interference with walls 216Z of base  
8 214 causes slide valve 250 to move into a position such that channel 256 of slide valve 250 is aligned  
9 with central bore and liquid can pass through ball joint 216 and into the patient through the cannula  
10 214C extending downward from the base 214. The use of the slide valve makes the first septum of  
11 the previous embodiments unnecessary, and therefore a needle on fluid connector 224 is, likewise,  
12 unnecessary. Instead, the embodiments set forth in this set of drawings uses gaskets where the  
13 channel of the fluid connection unit meets the rotating joint. The gaskets help provide a fluid tight fit  
14 with the fluid connector 224 to the ball joint 216 when the ball joint and fluid connector are engaged.

15 Yet another embodiment of the present fluid infusion assembly 310 featuring a unique  
16 pivoting joint concept is illustrated in Figs. 13 through 13K. In these figures the assembly is shown  
17 with the connection unit 324 attached to the infusion unit 311 in the second fluid delivery position. It  
18 should be understood that initially the infusion unit must be inserted in and attached to the patient's  
19 body as described with the previous embodiments. With the details of the earlier embodiments  
20 understood, this embodiment is seen to provide a one piece base 314 at least partially cut out to  
21 receive part of a pivoting joint 316 (see Figs. 13D and 13E). Pivoting joint 316 lays in base 314 and  
22 is partially engaged with a one piece cover 322 for engaging support arms 316B. Note in Fig. 13K  
23 that connection unit 324 includes arms 324A that will engage slots 314A of base 314 (see Figs. 13E  
24 and 13F) and also includes needle 326 and feed tube 328. As seen in Fig. 13D, pivoting joint 316 is  
25 seen to have a first septum 318 and second septum 320. The first septum is held in place in the  
26 rotating joint by means of a cap 318A. In Fig. 13I the two channels or bores 316H and 316I within  
27 the rotating joint may be seen, the bores are functionally equivalent to those seen in earlier rotating

1 joints. In Fig. 13J, cover 322 can be seen with cutouts for at least partially enclosing the pivoting  
2 joint and legs for engaging the base.

3 Figs. 14, 14A and 14B illustrate yet another alternative preferred embodiment of the present  
4 fluid infusion assembly 410 having a "T" shaped rotating joint 416. Here it is seen that alternate  
5 preferred embodiment of fluid injection assembly 410 has a base 414 and a pair of covers 422' and  
6 422" which together will enclose a cylindrical portion 416A and cylindrical support legs 416B of the  
7 "T" joint in a manner that will allow the "T" joint 416 to pivot from a down position where fluid can  
8 be carried through fluid connector 424 into "T" joint 416 and down through cannula 414C into the  
9 patient. In an up or vertical position (not shown) a handle may engage the unit to insert the fluid  
10 injection assembly onto the patient. This alternate preferred embodiment also features a lock  
11 mechanism 417.

12 In some circumstances, it is desired to not have a fluid flow path through the rotating  
13 member, but rather to utilize the rotating member principally for its ability to properly align the fluid  
14 infusion connection unit with the infusion unit attached to the patient's body. Thus, yet another  
15 embodiment 510 of the present invention is illustrated in Figs. 15 through 15D.

16 With an understanding of the previous embodiments, it will be seen that Fig. 15 is a cross  
17 sectional, side elevation view of another embodiment of the infusion unit 511 with an emplacement  
18 member 530 attached thereto. The needle 532 of the emplacement member 530 is affixed to head  
19 530A and passes through septum 518 attached to base 514 by septum locking cap 519. The needle  
20 532 then passes through cannula 514C and extends beyond the distal end of the cannula. The use of a  
21 separate septum 518 with a locking cap 519 considerably reduces manufacturing costs and ensures  
22 flexible, pliable septum.

23 It should be noted that the rotating member 516 is sandwiched between cover 522 and base  
24 514, as has been discussed with previous embodiments. However, in this embodiment 511, the  
25 rotating member 516 is in an initial down storage position without the fluid connection unit 524  
26 attached. The engagement arm 516C has a longitudinal axis,  $A_R$ , which in this initial storage position  
27 is perpendicular to the longitudinal cannula axis,  $A_C$ , as seen in Fig. 15.

1 Figs. 15A and 15B show the assembly 510 with the emplacement member 530 discarded and  
 2 the fluid infusion connection unit 524 attached to the rotating member 516. The connection unit 524  
 3 has been slightly rotated from a first position where the longitudinal arm axis  $A_R$  of the rotating  
 4 member attachment arm 516C was parallel to the longitudinal cannula axis,  $A_c$ . In this first position  
 5 the connection unit 524 is easily attached to the rotating member 516 by aligning the connection unit  
 6 alignment key 513 with the engagement arm key way 509 (Fig. 15) and urging unit 524 until the  
 7 engagement portion 524C is stopped against shoulder 549 of the rotating member 516. This ensures  
 8 positive, accurate alignment of the connection unit 524 with the infusion unit 511 when rotation to the  
 9 fluid delivery position is completed. Further, alignment accuracy is ensured by the cooperation of the  
 10 alignment hubs 537 (one on each side of the infusion unit 511) with the connection unit arm openings  
 11 551 (Fig. 15A). As the connection unit 524 is rotated downwardly towards a second "down" position  
 12 of the rotating member, the hubs 537 pass through the arm openings 551 to guide the connection unit  
 13 524 into the fluid delivery position.

14 The connection unit 524 is shown in Fig. 15B with a fluid delivery tube 528 attached to a  
 15 first end 543 and a rotating member engagement portion 524C on an opposite end. A needle 526  
 16 extends from the underside of the connection unit 524. When alignment is proper, needle 526 will  
 17 penetrate septum 518 allowing therapeutic fluid to flow to the patient.

18 Fig. 15A also illustrates the tactile "feel" mechanism of this embodiment 510. A pair of  
 19 locking bosses 524F are releasably engagable with boss coves 522M when the connection unit 524 is  
 20 "snapped" into a properly aligned fluid delivery position.

21 A top plan view of this embodiment 510 in the fluid delivery position is shown in Fig. 15C.  
 22 The alignment hubs 537 are properly positioned with arm openings 551, and the locking bosses 524F  
 23 are snapped into coves 522M. Fig. 15D is a cross sectional side elevation view of Fig. 15C taken  
 24 along line A-A. As may be seen, the longitudinal arm axis,  $A_R$ , is perpendicular to longitudinal  
 25 cannula axis,  $A_c$ . The needle 526 has penetrated septum 518 to allow fluid to be delivered through  
 26 tube 528 to the patient.

1           Although the invention has been described with reference to specific embodiments, this  
2     description is not meant to be construed in a limited sense. Various modifications of the disclosed  
3     embodiments, as well as alternative embodiments of the inventions will become apparent to persons  
4     skilled in the art upon the reference to the description of the invention. It is, therefore, contemplated  
5     that the appended claims will cover such modifications that fall within the scope of the invention.

1 CLAIMS:

2  
3 1. A system for subcutaneous delivery of a therapeutic fluid from a remote source into a  
4 patient's body comprising:

5 a main fluid infusion unit having a downwardly depending cannula extending from an  
6 underside of said unit, said cannula having a longitudinal cannula axis and a distal cannula end for  
7 insertion into said body of said patient;

8 a main fluid infusion unit emplacement member having an insertion needle, said insertion  
9 needle adapted to extend through said main fluid infusion unit and to extend beyond said distal  
10 cannula end when said system is in a first emplacement position;

11 an infusion fluid connection unit having a first end to removably receive a fluid delivery  
12 tube, said tube in fluid communication with said source of said therapeutic fluid through a first tube  
13 end; said connection unit having a rotating member engagement portion on a second end, said  
14 connection unit adapted to deliver said therapeutic fluid into said patient's body when said system is  
15 in a second delivery position;

16 a rotating member pivotably attached at a first end to said main fluid infusion unit, said  
17 rotating member having an engagement arm for receiving said rotating member engagement portion  
18 of said infusion fluid connection unit, said engagement arm having a longitudinal arm axis, said  
19 rotating member pivotable from a first position wherein said longitudinal arm axis is parallel to said  
20 longitudinal cannula axis and a second position wherein said longitudinal arm axis is perpendicular to  
21 said longitudinal cannula axis, whereby when said connection unit is attached to said rotating member  
22 and said rotating member is in said second position said system is in said second delivery position for  
23 delivery of said therapeutic fluid into said patient's body.

24 2. The system of claim 1 wherein said rotating member engagement portion further comprises a  
25 delivery needle and said rotating member further comprises a plurality of intersecting fluid channels.

26 3. The system of claim 2 wherein said rotating member further comprises a first septum.

1 4. The system of claim 3 wherein said rotating member comprises a second septum positioned  
2 such that when said rotating member is in a first position, said first and second septum are axially  
3 aligned with said longitudinal cannula axis.

4 5. The system of claim 4 wherein a first of said intersecting fluid channels is located in said  
5 engagement arm, said first septum is positioned within said first channel, and a second of said  
6 intersecting fluid channels is in communication with said cannula when said rotating member is in  
7 said second position

8 6. The system of claim 1 further comprising a locking member to releasably retain said rotating  
9 member in said second position when said rotating member engagement portion of said infusion fluid  
10 connection unit is attached to said main fluid infusion unit.

11 7. The system of claim 1 further comprising a boss cooperating with a cover to produce an  
12 audible or tactile indication that said rotating member is in said second position when said fluid  
13 infusion connection unit is attached to said main fluid infusion unit.

14 8. The system of claim 1 wherein said engagement arm of said rotating member extends above  
15 an upper surface of a body of said infusion unit when said rotating member is in said first position and  
16 does not extend above said upper surface when said rotating member is in said second position.

17 9. The system of claim 1 wherein said rotating member engagement portion has a guide for  
18 aligning said portion with said engagement arm of said rotating member.

19 10. The system of claim 1 further comprising a plug engageable with said engagement arm, said  
20 plug for engagement with said engagement arm when said delivery tube is disengaged from said fluid  
21 infusion connection unit.

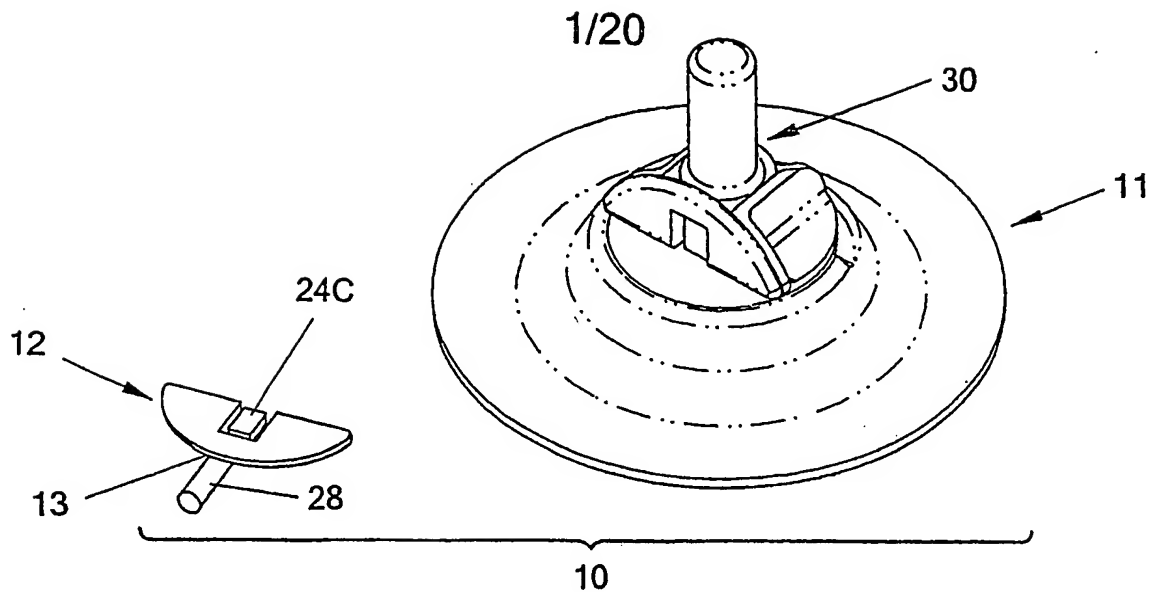


Fig. 1

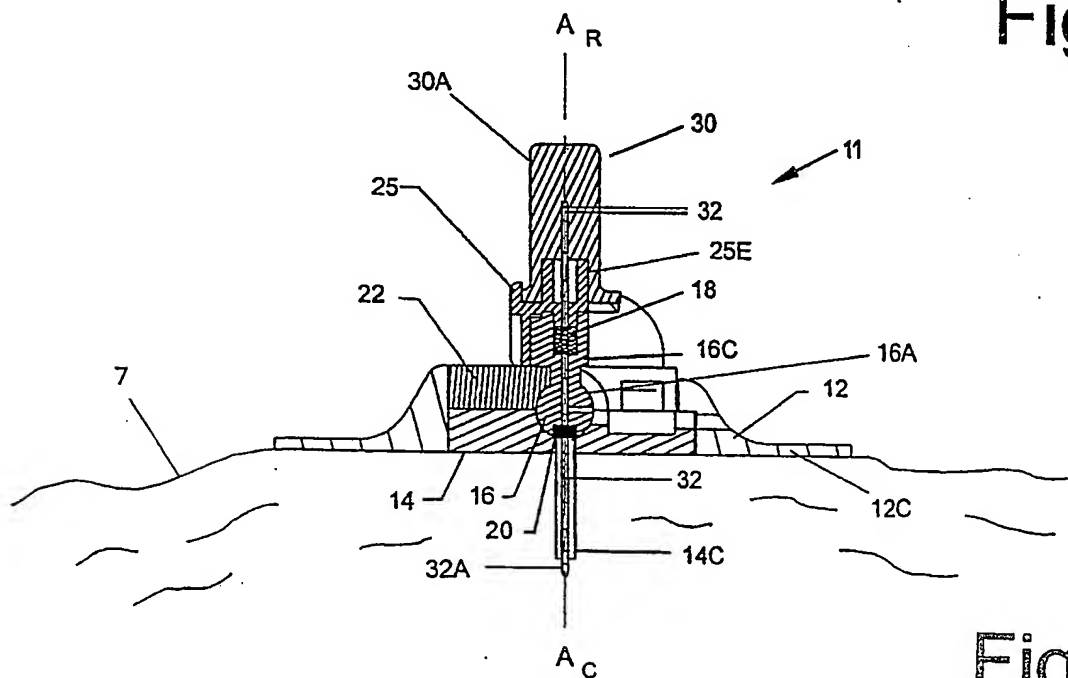


Fig. 1A

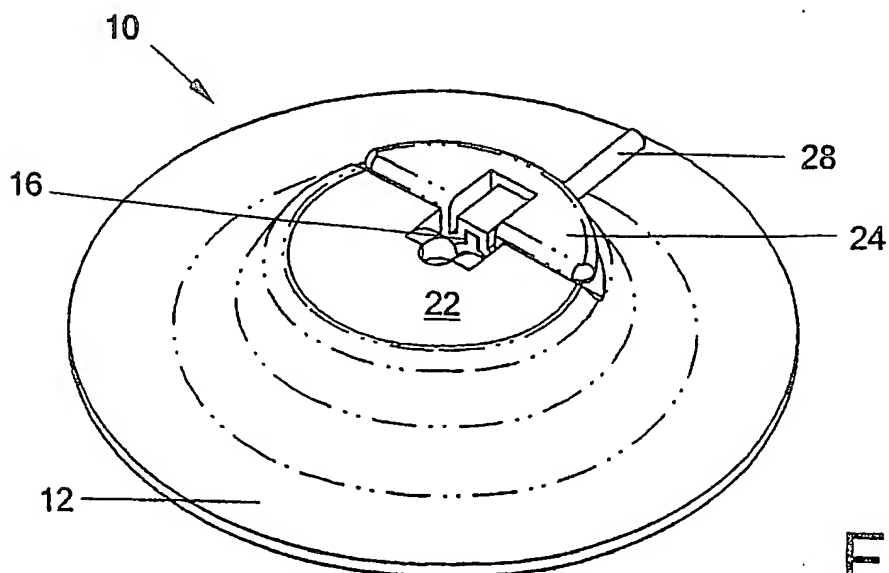


Fig. 2



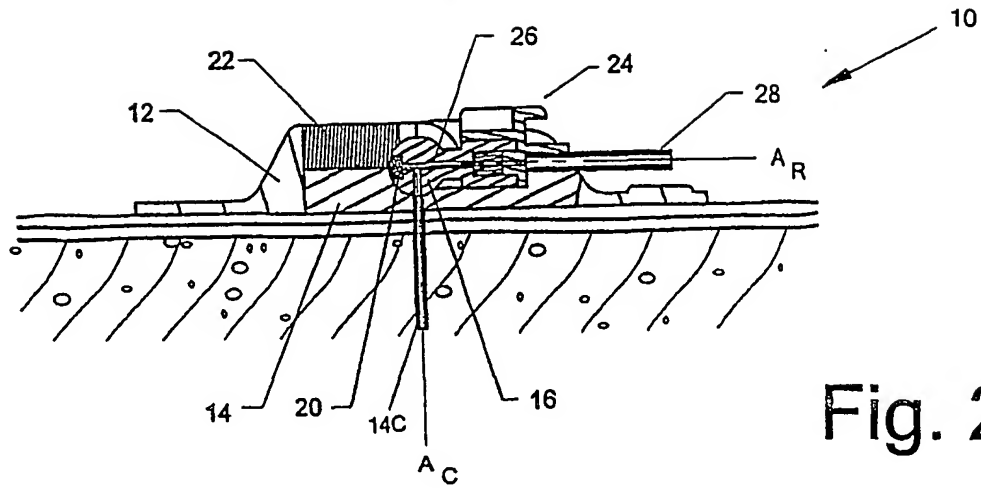


Fig. 2A

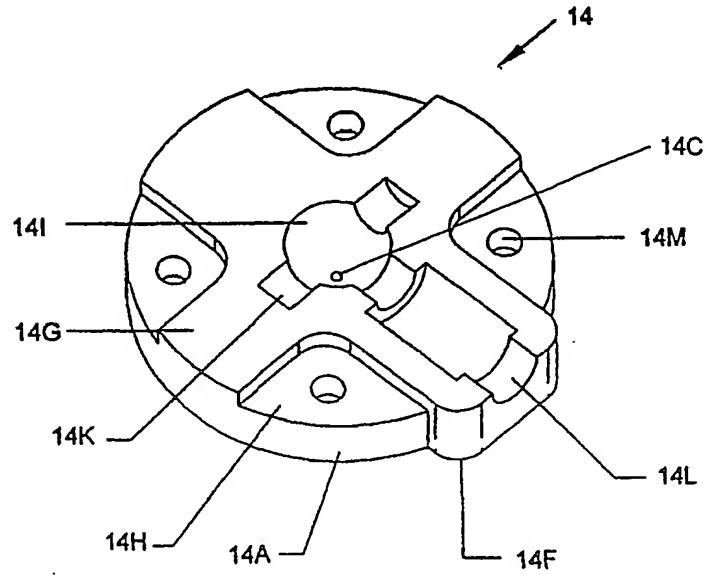


Fig. 3

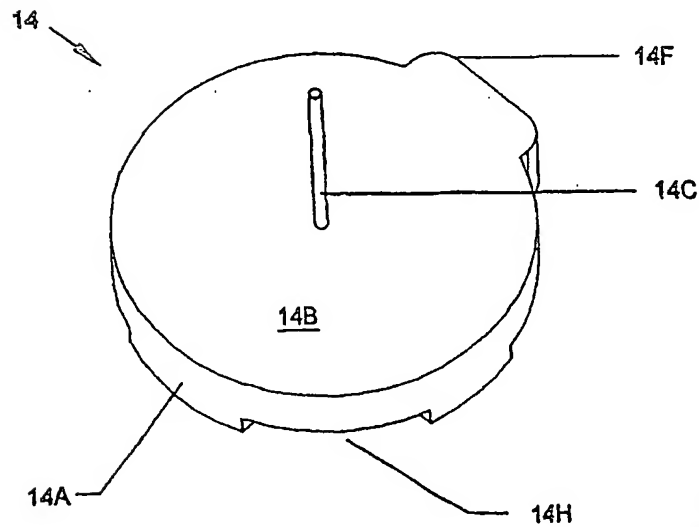


Fig. 3A

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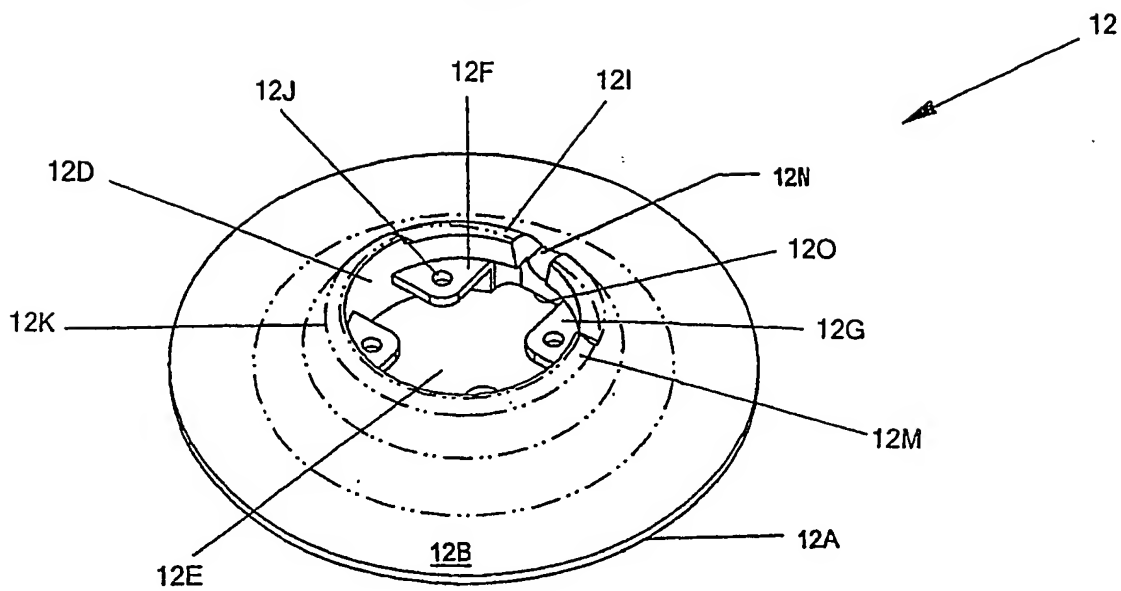


Fig. 4

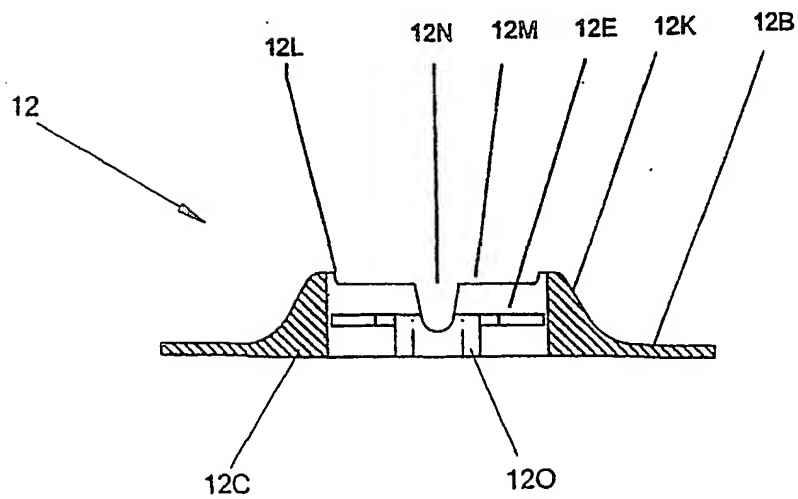


Fig. 4A

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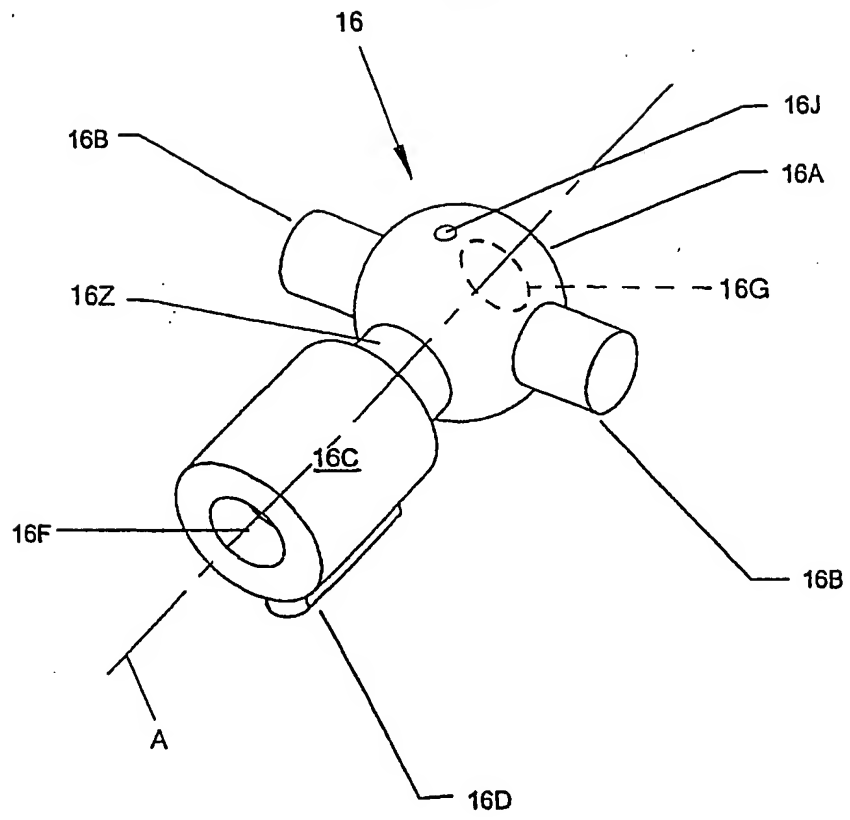


Fig. 5

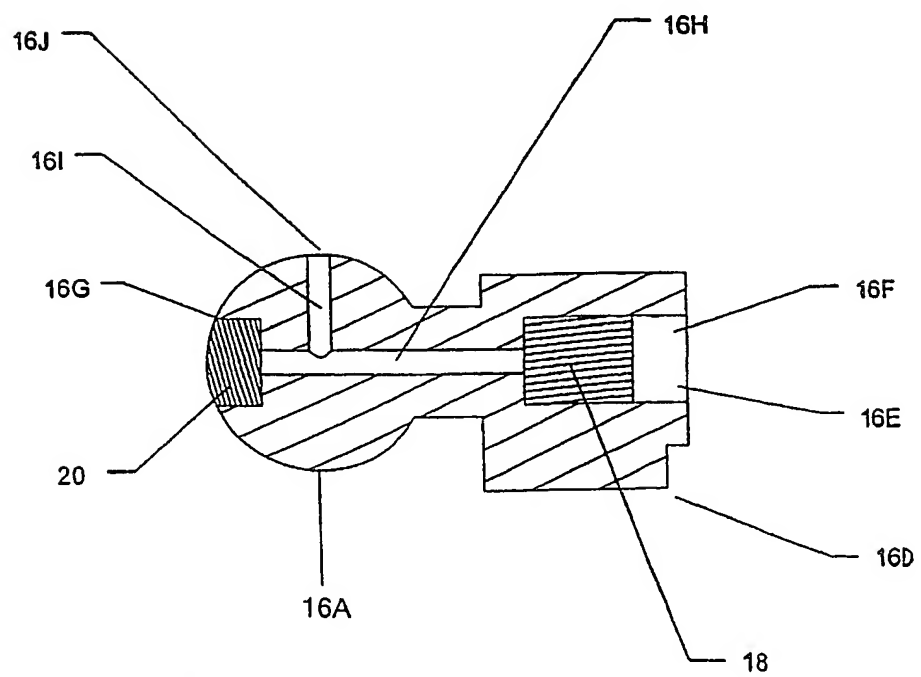


Fig. 5A

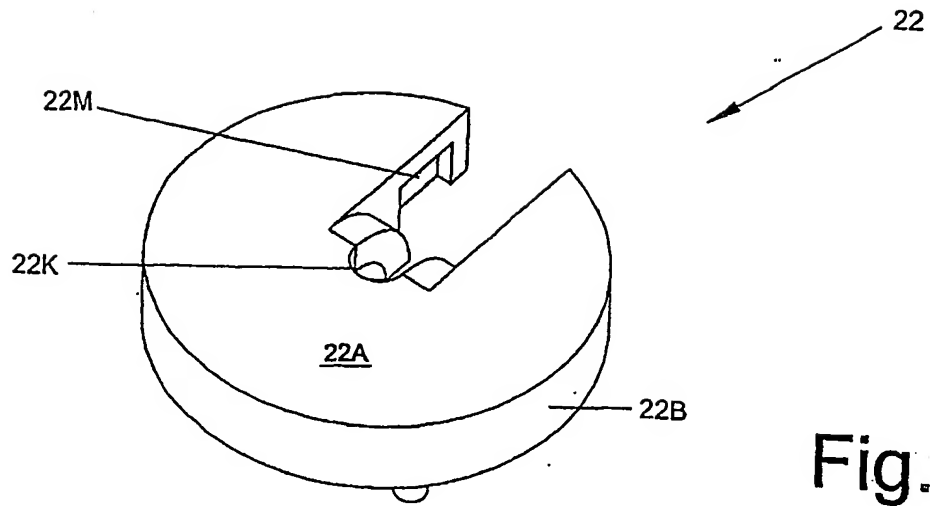


Fig. 6

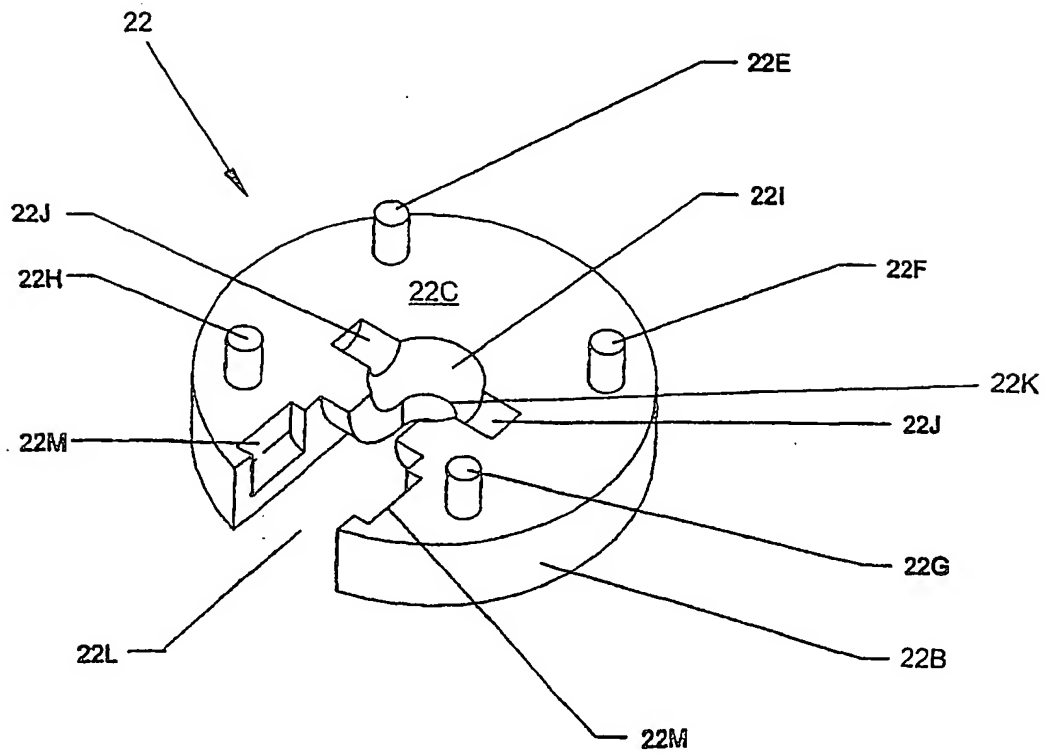


Fig. 6A

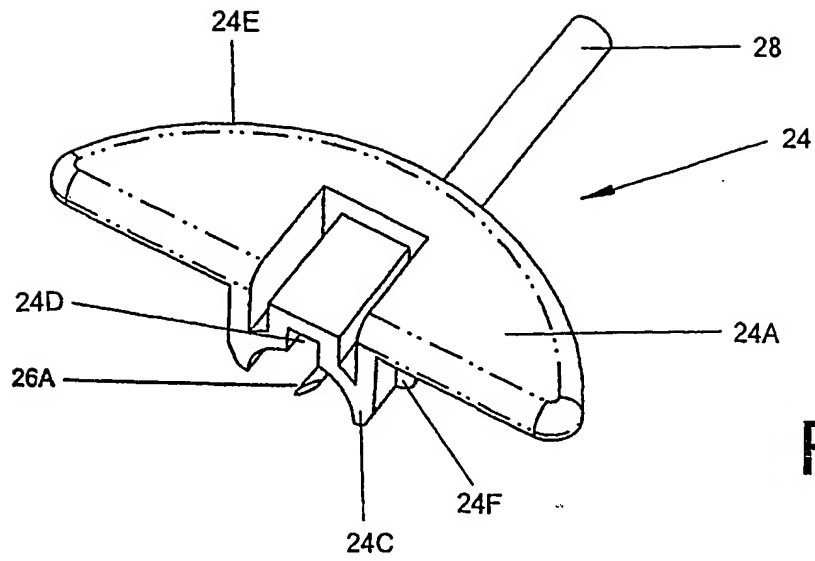


Fig. 7

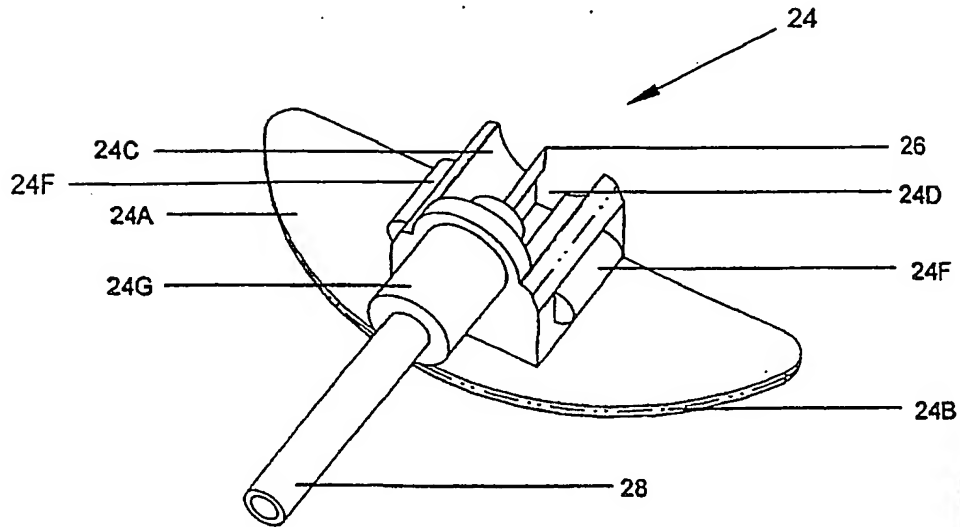


Fig. 7A

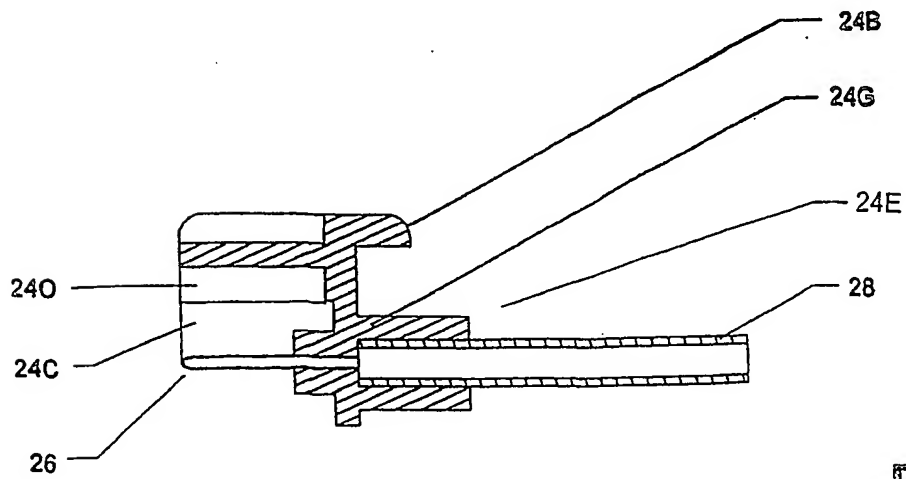


Fig. 7B

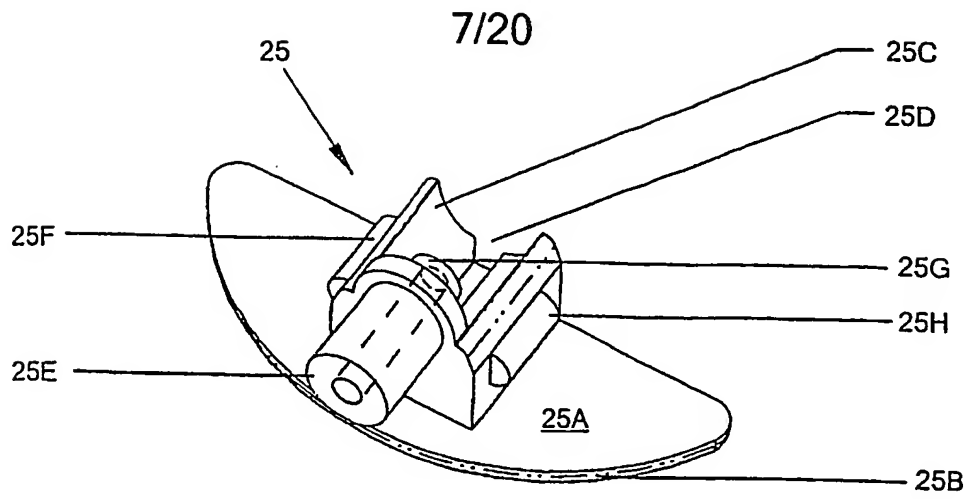


Fig. 8

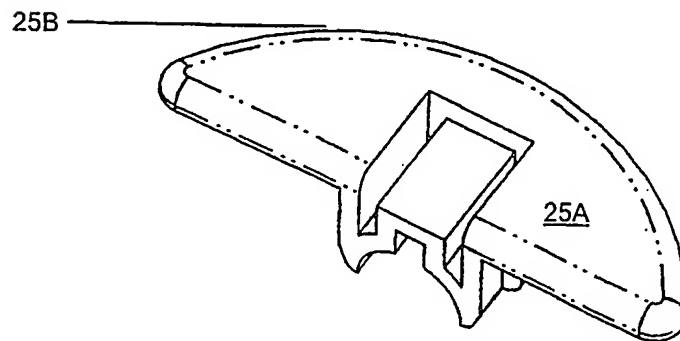


Fig. 8A

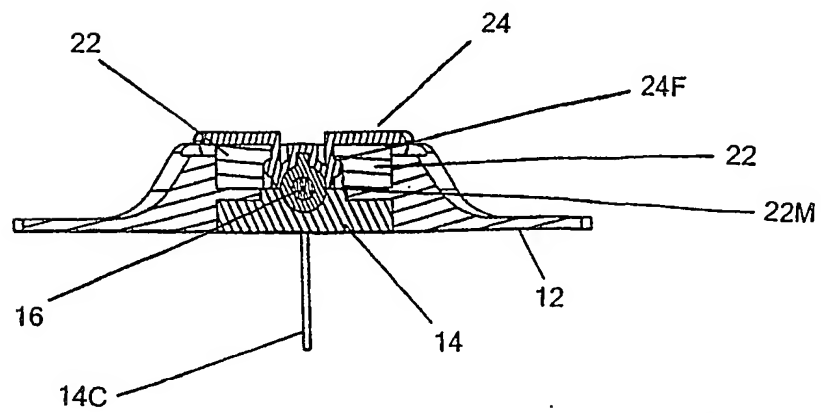


Fig. 9

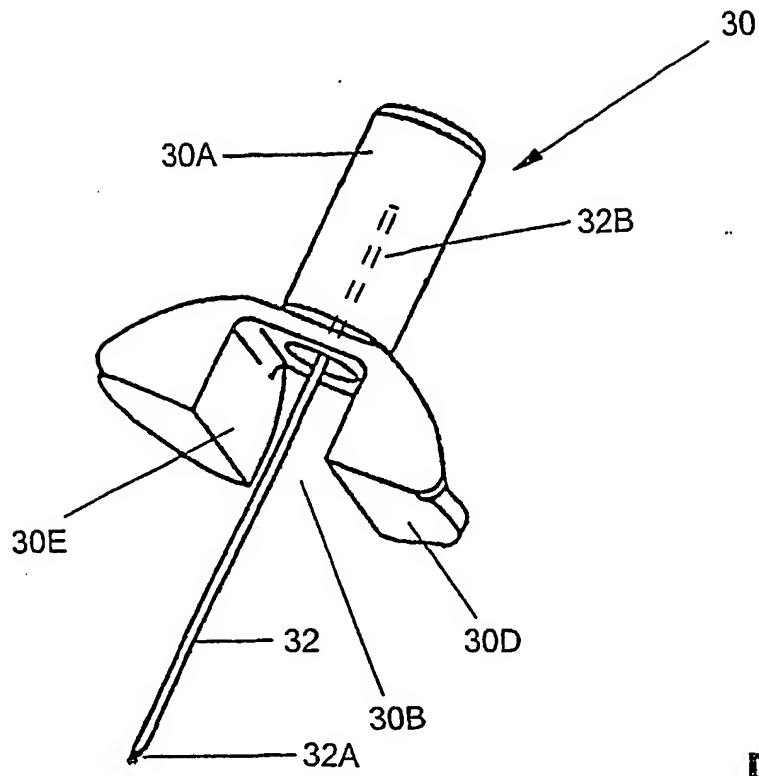


Fig. 9A

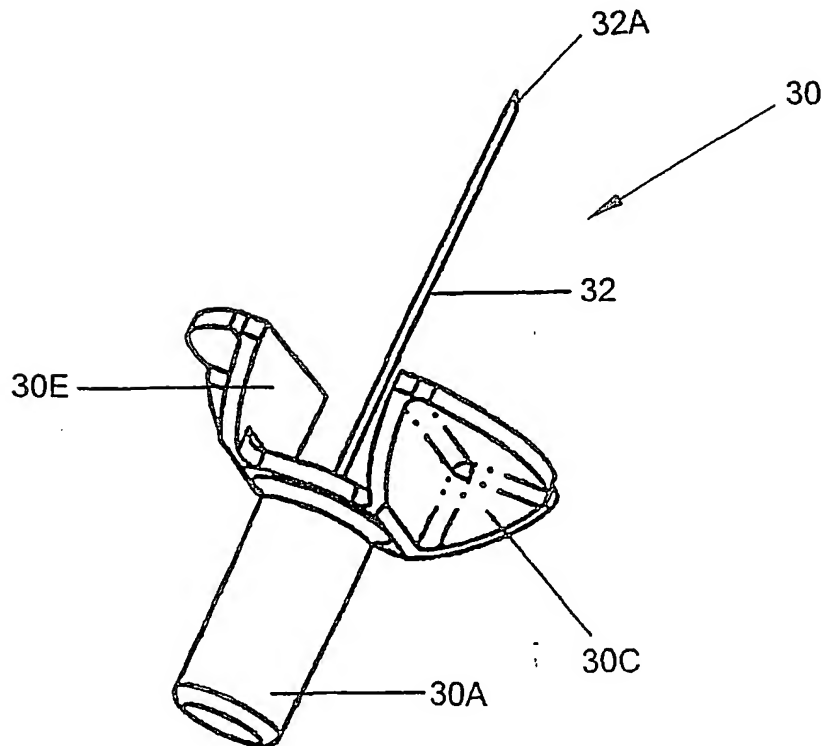


Fig. 9B

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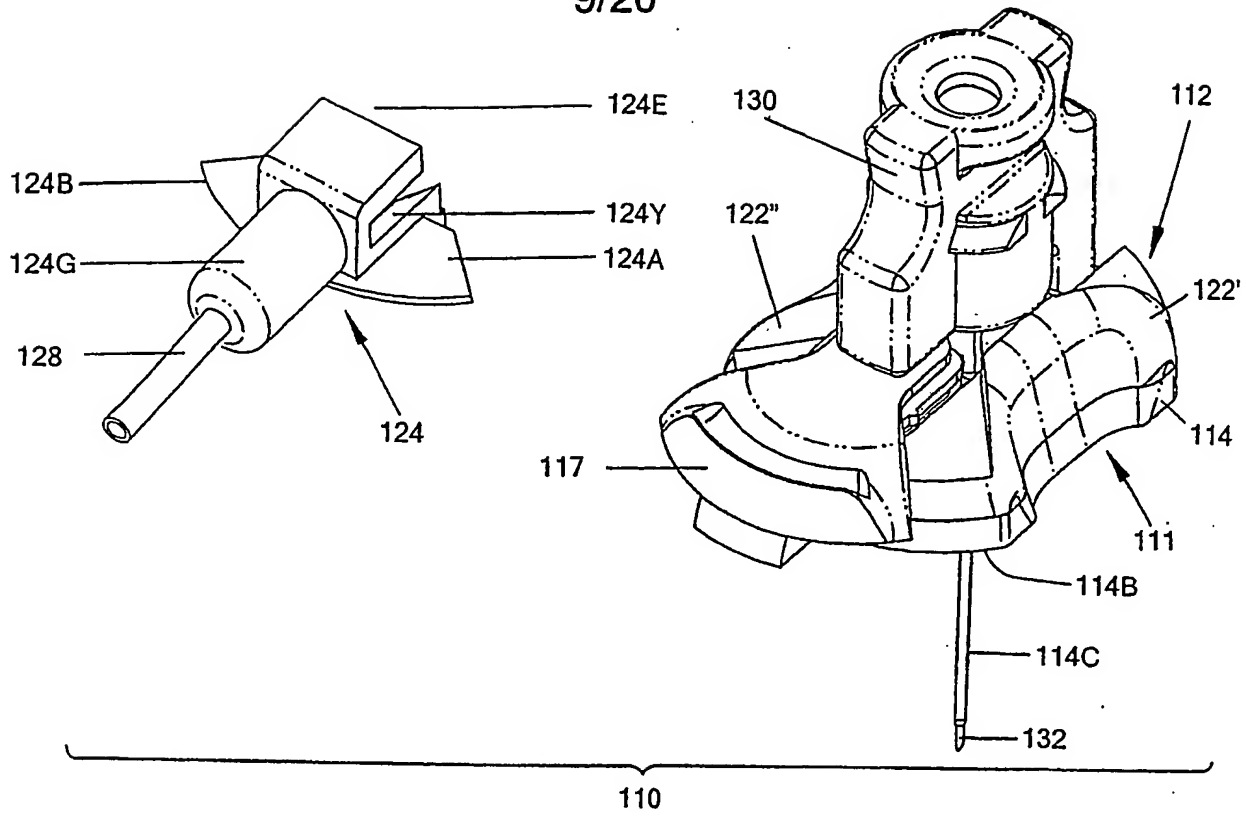


Fig. 10

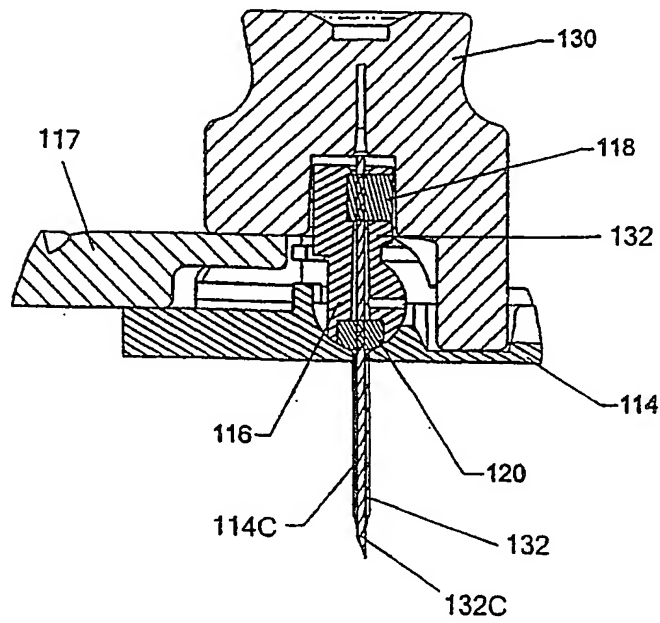


Fig. 10A



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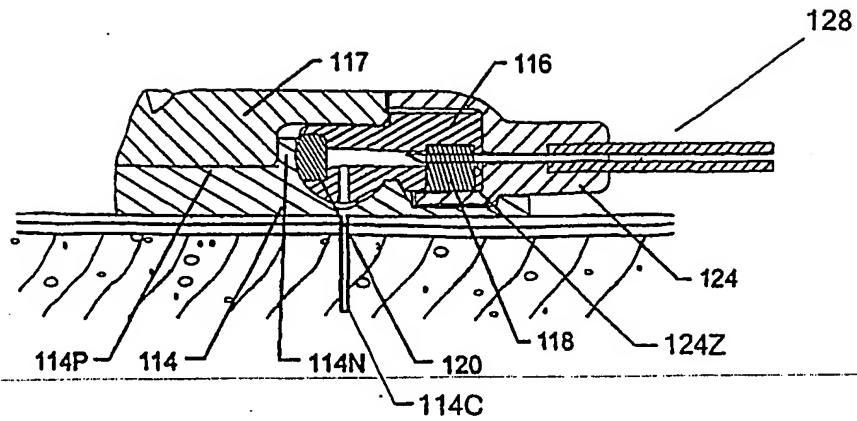


Fig. 10B

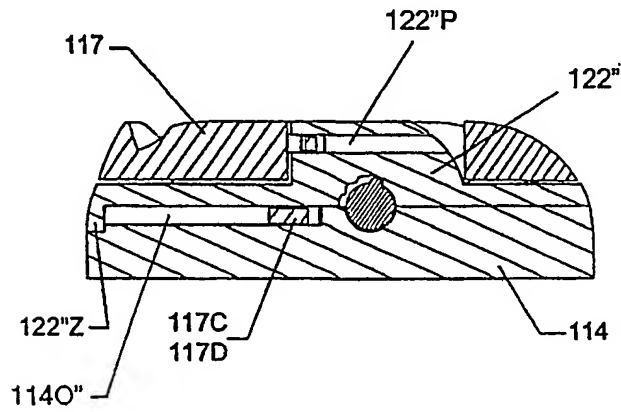


Fig. 10C

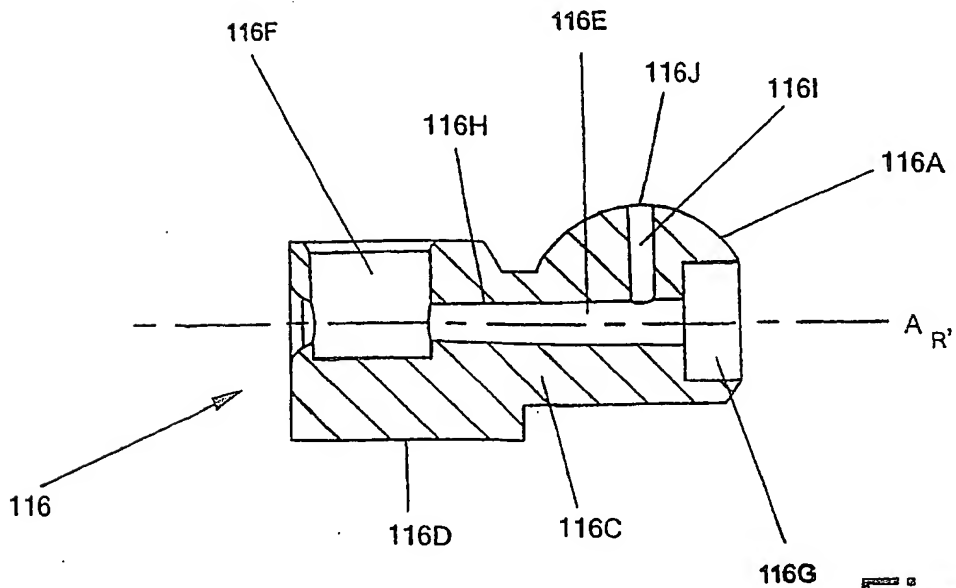


Fig. 10D

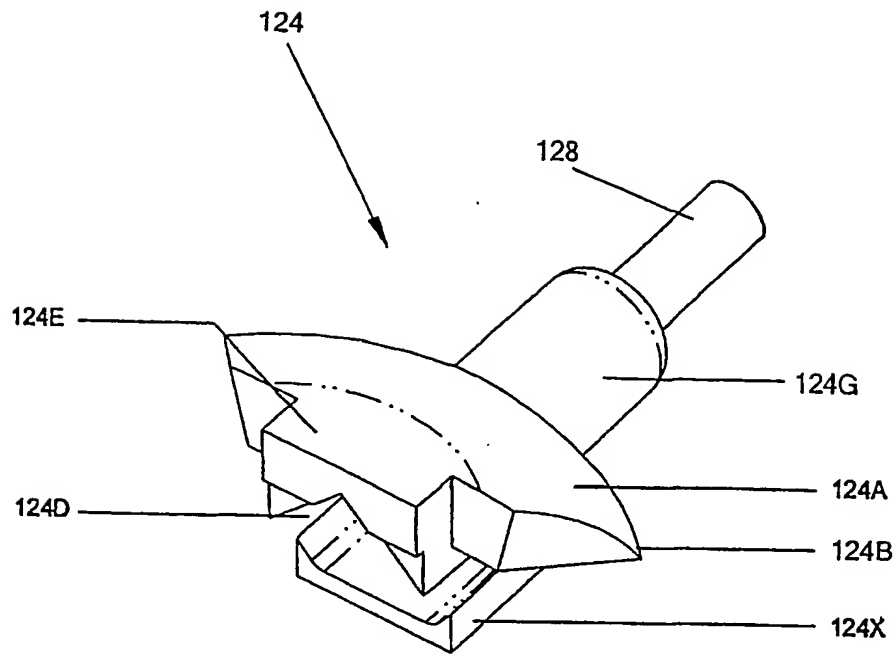


Fig. 11

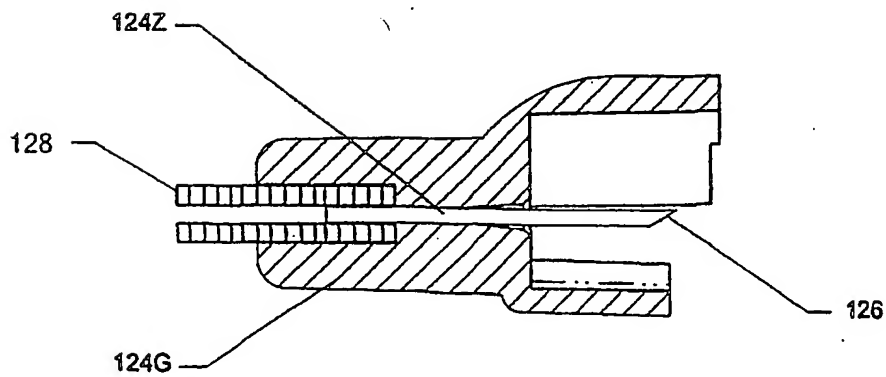


Fig. 11A

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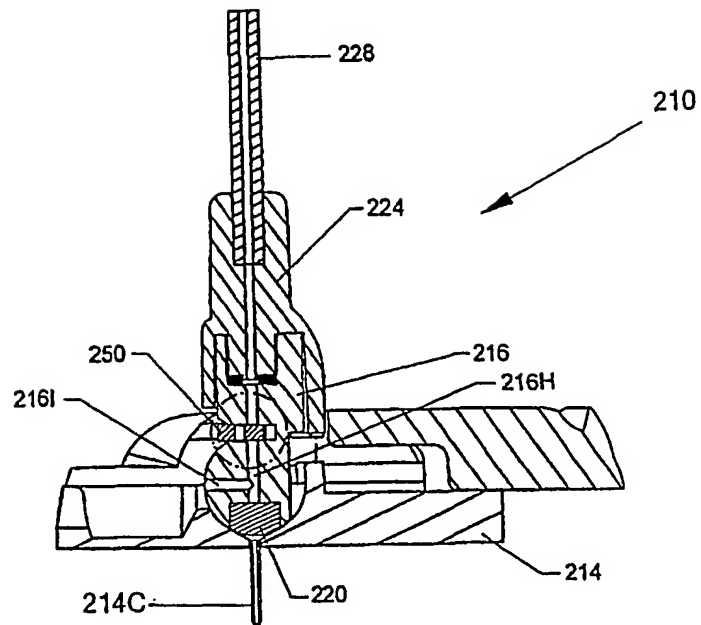


Fig. 12

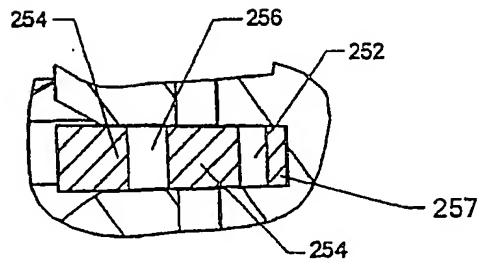


Fig. 12A

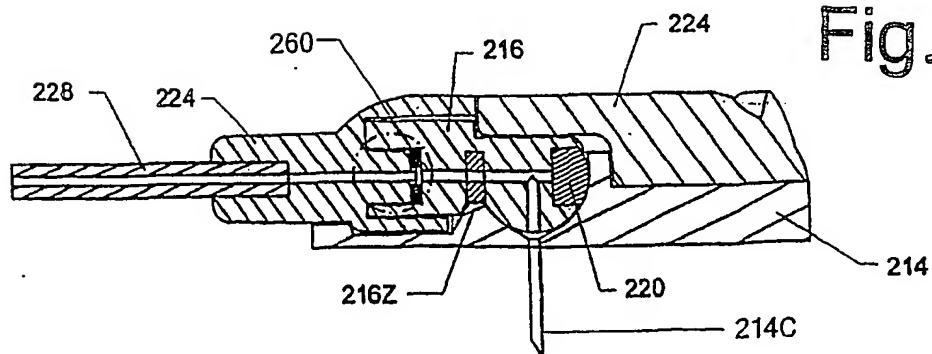


Fig. 12B

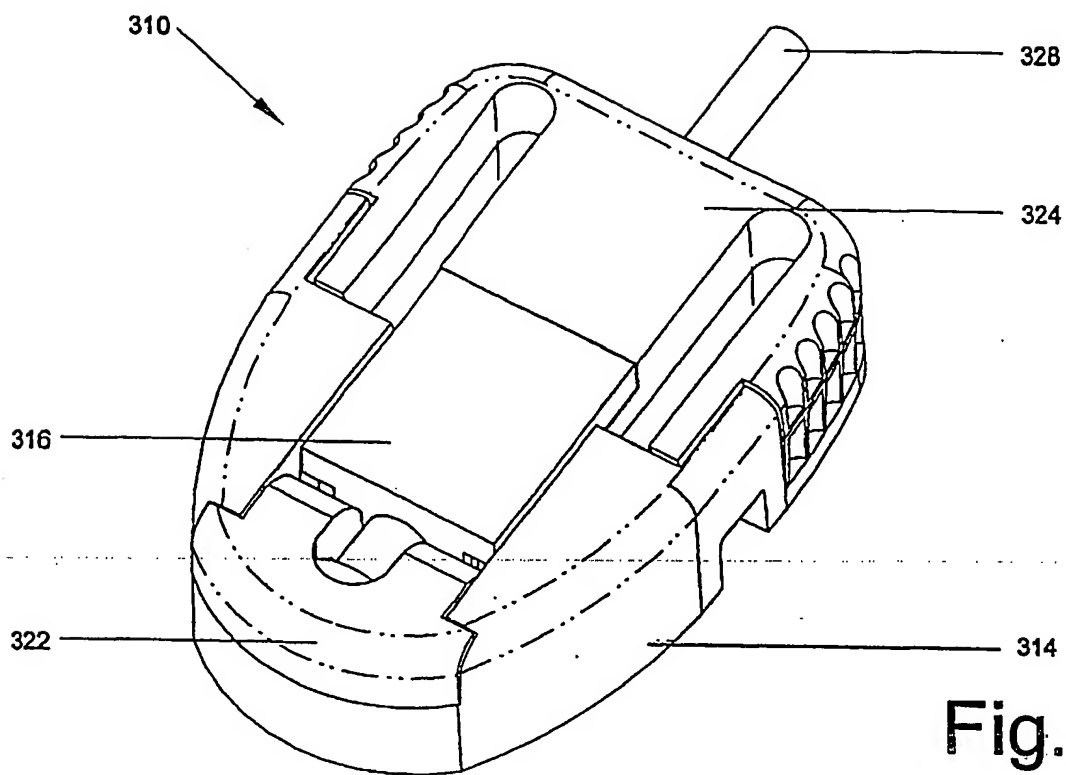


Fig. 13

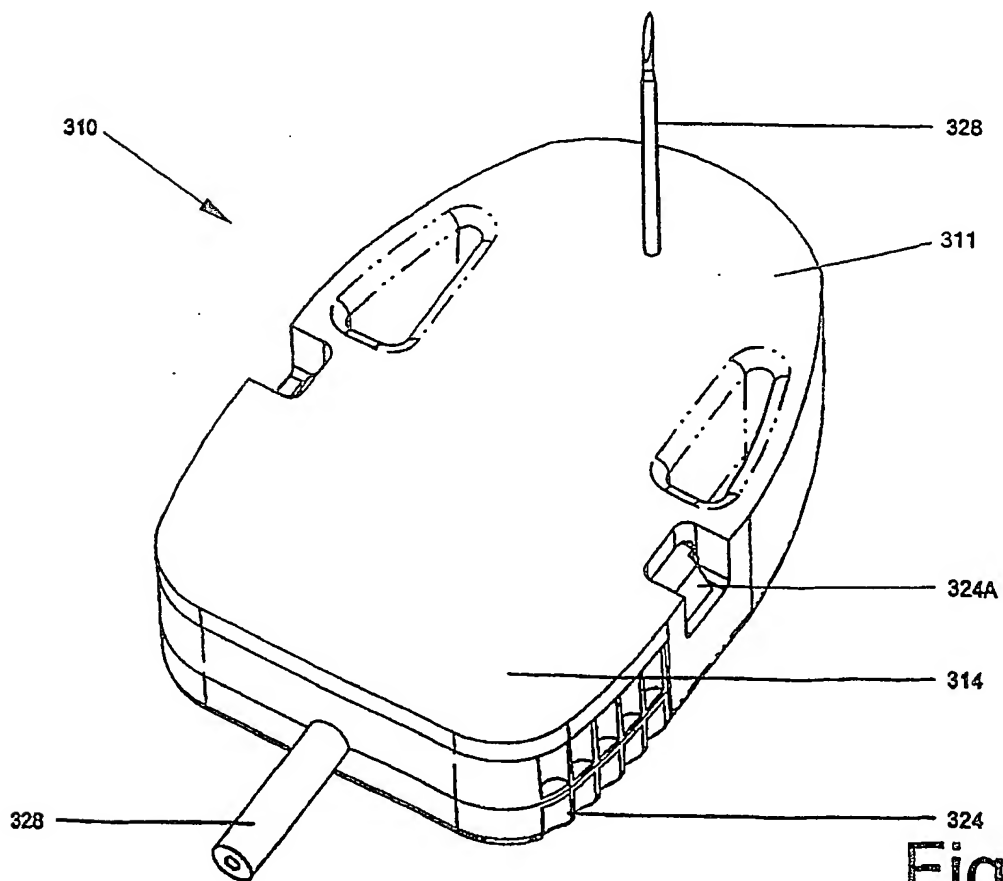


Fig. 13A

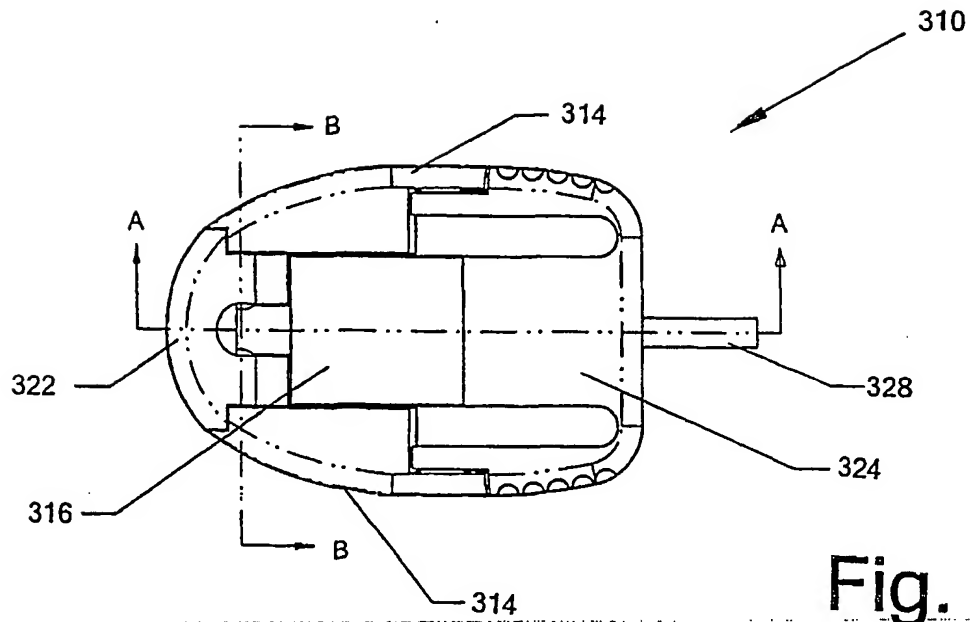


Fig. 13B

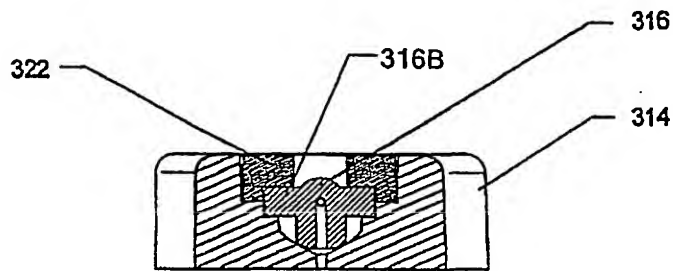


Fig. 13C

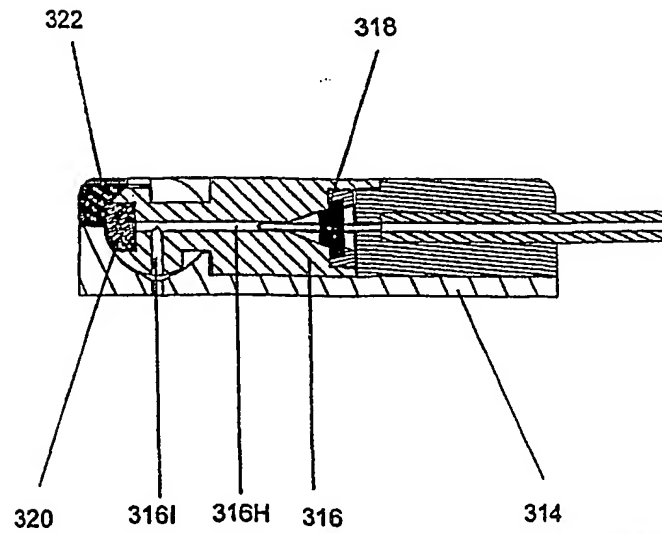


Fig. 13D

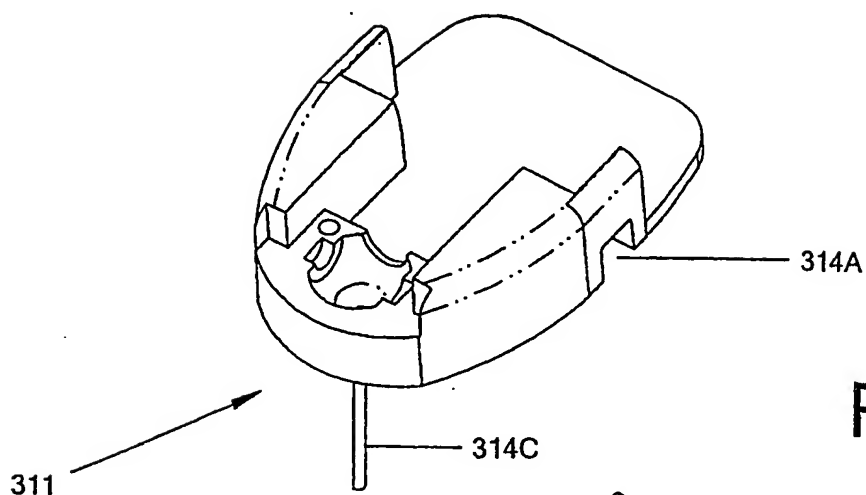


Fig. 13E

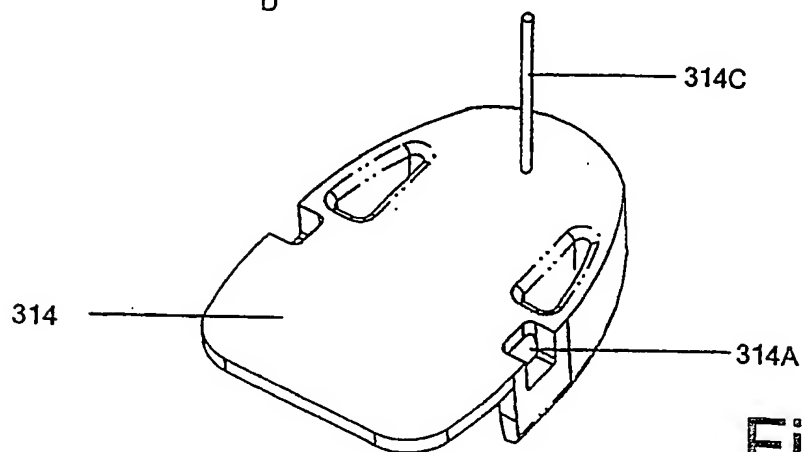


Fig. 13F

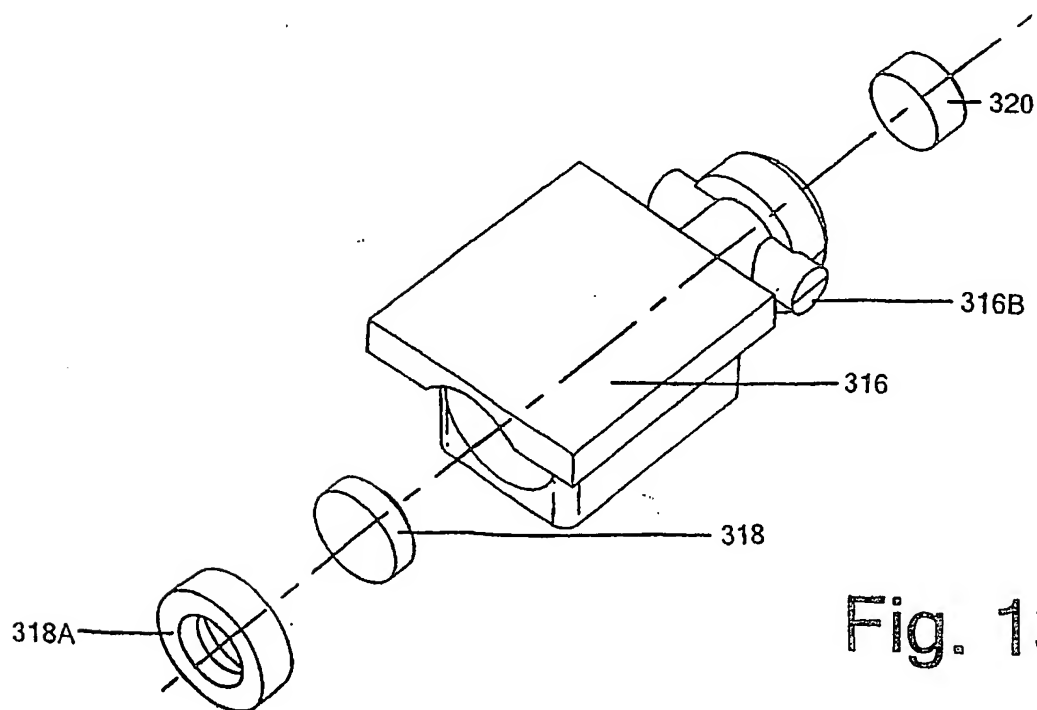


Fig. 13G

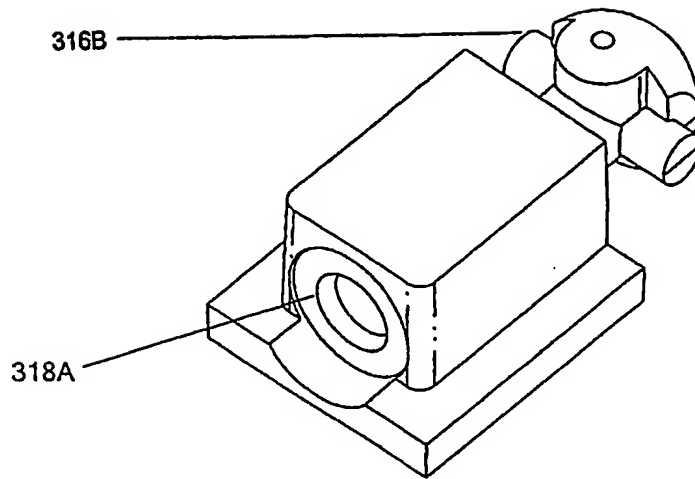


Fig. 13H

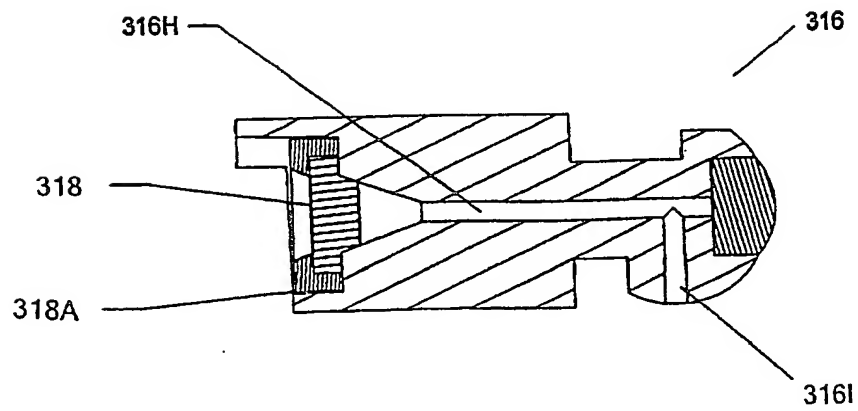


Fig. 13I

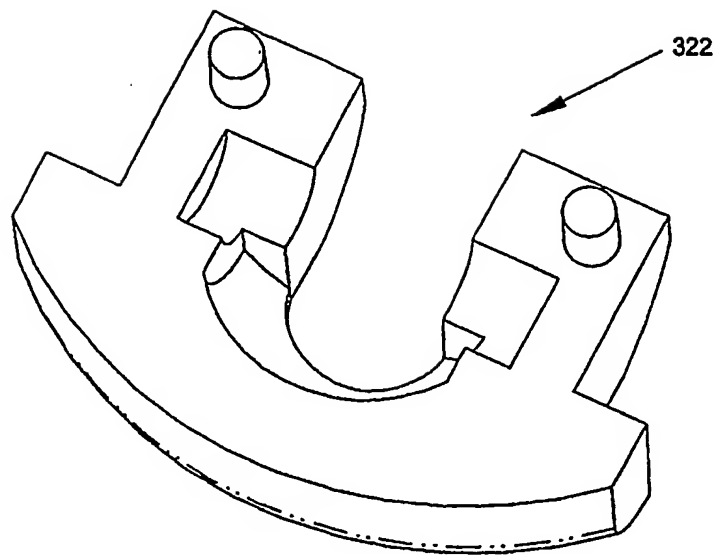


Fig. 13J

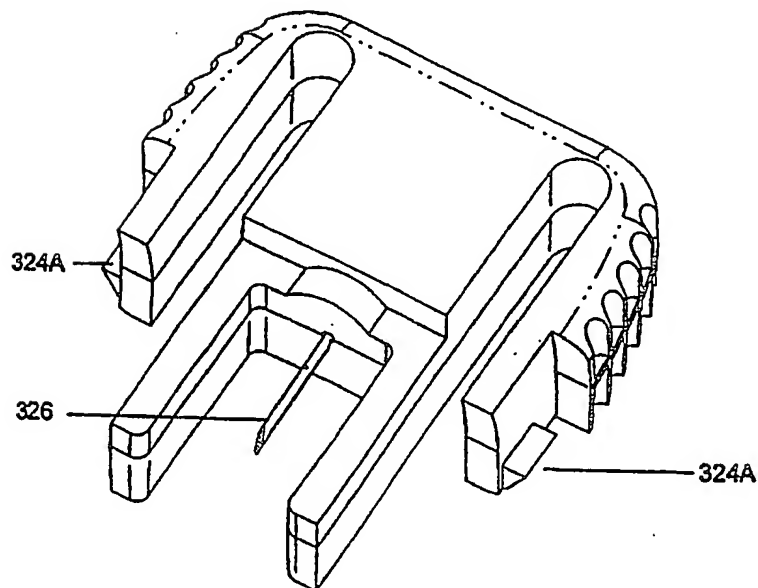


Fig. 13K



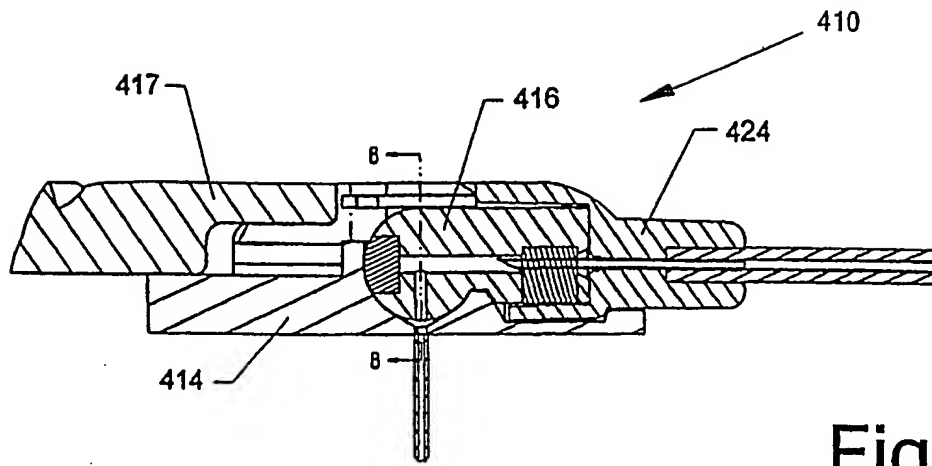


Fig. 14

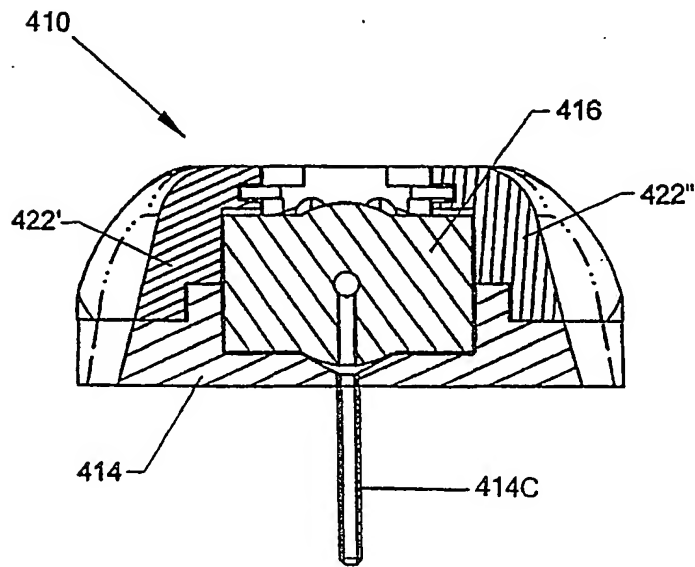


Fig. 14A

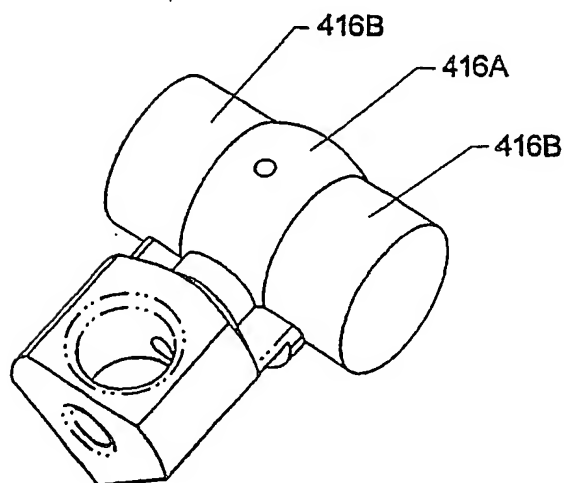


Fig. 14B

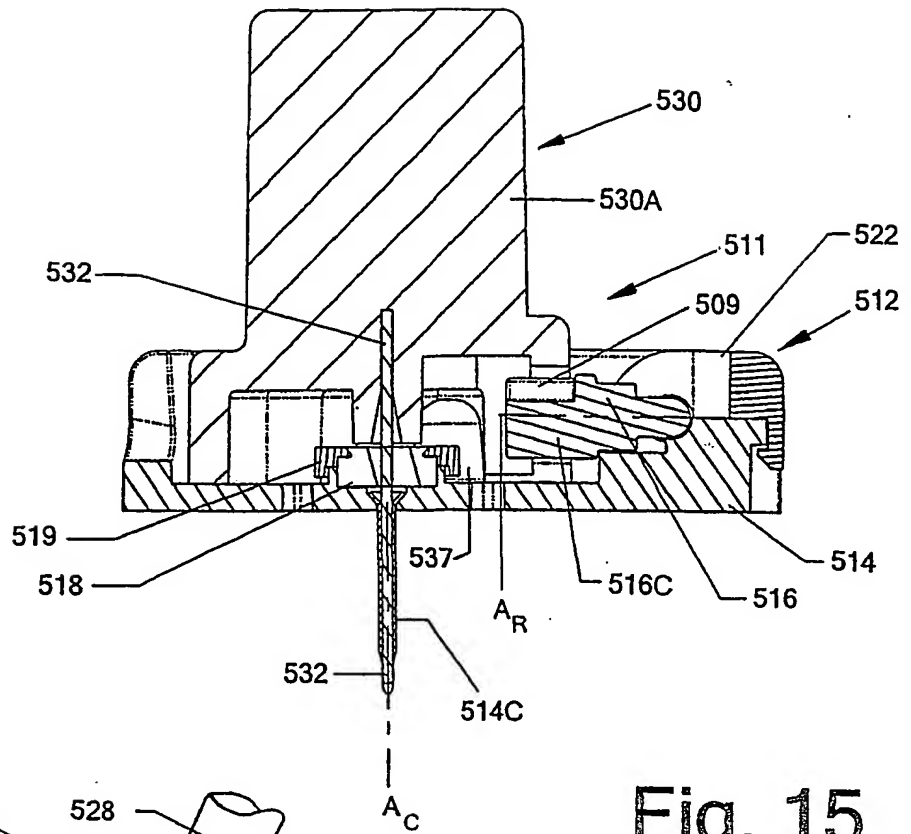


Fig. 15

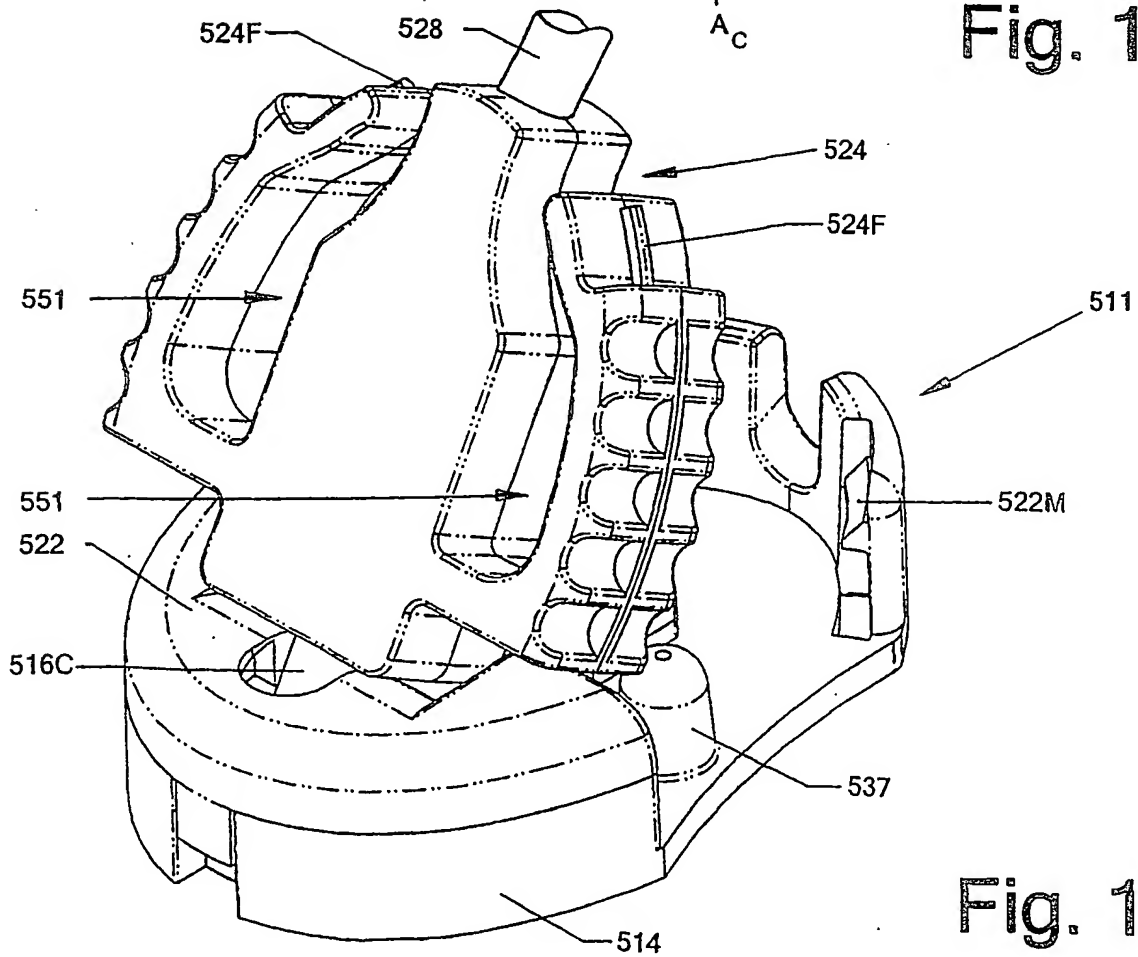


Fig. 15A

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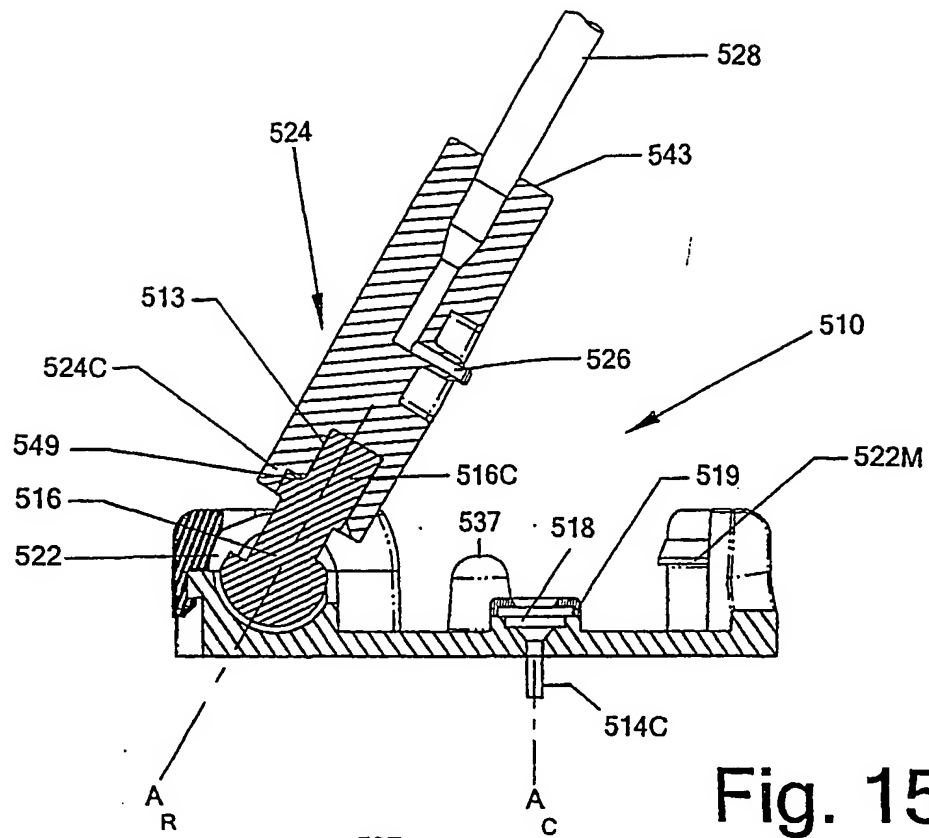


Fig. 15B

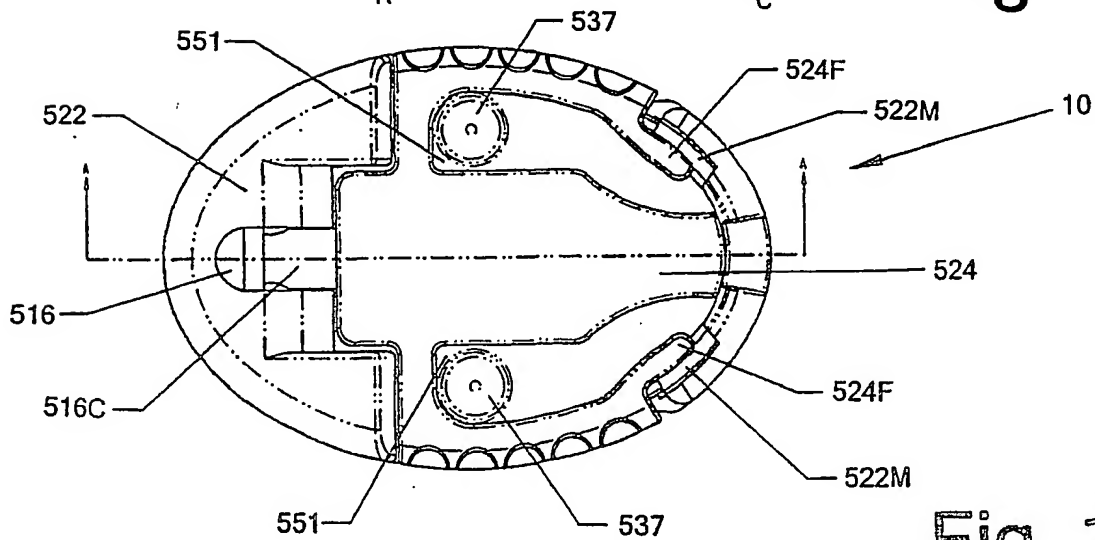


Fig. 15C

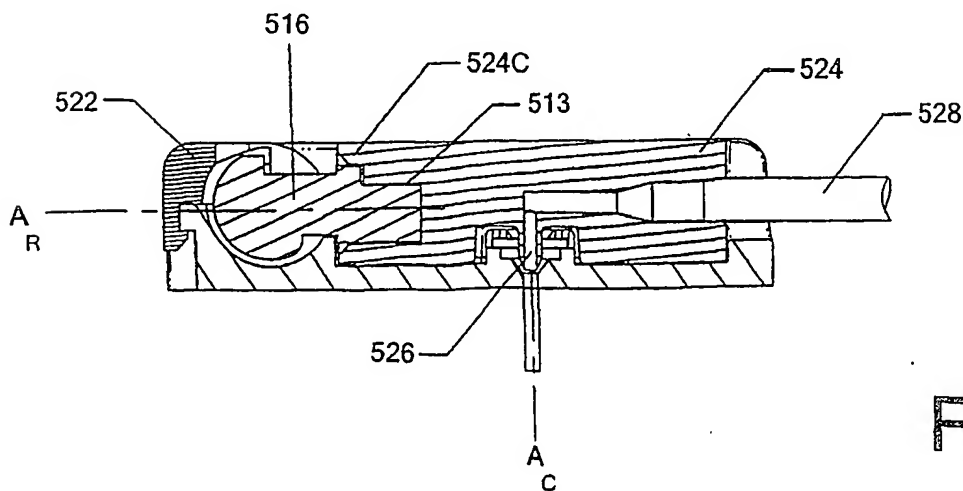


Fig. 15D



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